Literature Review

Automated Data Sources for Ambulatory Care Effectiveness Research

U.S. Department of Health and Human Services
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Agency for Health Care Policy and Research

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Foreword

The Agency for Health Care Policy and Research (AHCPR), through its Office of Science and Data Development, has been working to provide greater access to health care data bases, uniform definitions, common reporting formats and linkages, and standards to ensure security, confidentiality, accuracy, and appropriate maintenance of data.

This literature review should provide medical effectiveness researchers with a valuable tool for identifying and accessing automated medical records on ambulatory care.

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Preface

Medical effectiveness studies that involve use of automated ambulatory medical records constitute an emerging field. To date, there has been little guidance to assist researchers in locating previous studies that employed the type of data of interest. This literature review was designed to help fill that void. It represents a systematic and objective description of the available literature on medical treatment effectiveness in ambulatory settings in which the researchers have relied substantially on computerized medical records. The review includes studies that involved the use of computerized records to identify practice patterns (particularly the effects of these patterns on patient survival, quality of life, and costs of care).

In collecting and describing these resources, emphasis was placed on the characteristics of the record system and the methodology of record search and data extraction. Based on information derived from the literature review, the reader will be able to identify computerized ambulatory record systems suitable for research, including systems in use in countries other than the United States.

This literature review provides a basis for discussions of linkages between "certain types of data" to proceed based on the general content and levels of linkages possible with existing data bases. The descriptions of the data bases also will facilitate an analysis of the usefulness of combining the information contained within different data bases to address additional medical effectiveness issues.

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Executive Summary

A comprehensive review of the literature was performed to identify automated ambulatory medical records systems (AAMRSs), issues relating to AAMRSs, and studies of medical effectiveness that have used automated medical records. In addition to system descriptions, two major categories of literature and materials were identified: (1) empirical studies that are based primarily on AAMRSs and (2) descriptive literature on policy, methods, and technology, using MEDLINE, SOCIOFILE, CATLINE, the Directory of Published Proceedings and Proceedings in Print, as well as Congressional Record Abstracts (CREC), PAIS, and LEXIS. Uncataloged materials—such as recent journals, books, abstracts, and conference proceedings—also were reviewed, and personal contacts were explored to identify:

- AAMRS descriptions.
- Studies using computerized medical records in ambulatory care settings, especially those detailing practice patterns, process of care, outcome, and costs, in addition to those using computerized medical records that can be adapted to ambulatory care settings.
- Outcome studies including survival, life quality, satisfaction, and health status.
- Technology issues including hardware, software, research strategies, retrieval mechanisms, and query languages.
- Methodological issues including research questions, definitions, operations manuals, quality control studies, analytic techniques, and statistical considerations.

Materials were gathered and coded and are described in this review. Although medical effectiveness studies that use automated ambulatory medical records are of major interest to the Agency for Health Care Policy and Research (AHCPR), only a few such studies were found, perhaps because the field is an emerging one.

Chapter 1 of this literature review covers ambulatory medical record systems, and Chapter 2 reviews medical effectiveness and health services research studies and issues, as well as quality assurance articles. Chapter 3 describes the use of automated medical records for decisionmaking. Chapter 4 addresses legal, confidentiality, and privacy issues; and Chapter 5 identifies methodological issues associated with the use of automated ambulatory medical records. Chapter 6 describes selected automated ambulatory medical record systems.

1. Ambulatory Care Records Systems and Data Bases

Introduction

Ambulatory care services are provided to nonhospitalized patients in:

- Hospital-based clinics and programs.
- Homes, through home health agencies.
- Private physicians' offices.
- Prehospital emergency medical systems.
- Community health clinics.
- Free-standing clinics.
- Health maintenance organizations (HMOs).

Because of the numerous changes in the health care system, the most important of which is the introduction of the Federal prospective payment movement, there has been a shift of care from the hospital inpatient setting to the ambulatory care setting. Evidence of the shift is shown by the following (Matson and McDougall, 1990):

- The number of visits to outpatient sites exceeds the number of short-term, inpatient care days on a nationwide basis.
- Total hospital revenues from outpatient services increased from 12 percent in 1983 to 26 percent in 1988, an increase of 117 percent.
- It is predicted that by 1995 the majority of hospitals will derive 50 percent of their revenue from outpatient services.
- The number of free-standing ambulatory care providers is expected to increase from 19,516 in 1980 to 39,550 in 1990.

It is anticipated that the increased use of ambulatory care services will dictate the need for information systems with integration among ambulatory, inhospital, and ancillary hospital systems, and this area should be one of growth in the 1990s. The benefits of computers to health care delivery have been described, and the increased use of computers and information systems in the health care sector generally, and the medical record specifically, has been forecasted since the late 1960s (Shortliffe and Perreault, 1990).

The medical record summarizes a patient's medical history and documents the observations, diagnostic conclusions, and plans of health personnel that is supposed to support patient care and clinical research (Shortliffe and Barnett, 1990). Several arguments support the need for automated ambulatory care medical records. Although the contents of the hospital medical record are mandated, the contents of the ambulatory record may not be as stringently regulated (Mesel and Wirtschafter, 1976). Several authors note that paper ambulatory care records frequently contain poorly organized data, inaccurate information including diagnostic coding, and lack of documentation on key aspects of care. Acknowledged weaknesses include:

- Lack of standardization in content and format.
- Inaccessibility.
- Incompleteness.
- Inaccuracies.

In reaction to the difficulties with the paper medical record, Weed introduced the Problem-Oriented Medical Record (POMR) in 1968 that structured the medical record by problem rather than by strict chronology. In the early 1970s, Fries introduced the Time-Oriented Record (TOR) that collects patient encounters in an array over time, by date, so problems can be viewed across time (Fries, 1972). These approaches to the medical record became the basis of early automated medical records systems. For example, the TOR became the basis of other record systems, including the American Rheumatism Association Medical Information System (ARAMIS), discussed below.

Using the POMR, Weed and Zimny (1989) developed PROMIS (the Problem-Oriented Medical Information System). This system—which was to replace all paper recordkeeping, was technologically advanced, and included a touch screen and other innovative features—is no longer used. However, the concept of the problem-oriented record is

considered to be a major contribution by Weed. More recently, Weed (1991) developed a problem-knowledge coupler for microcomputers to assist clinicians in organizing patient data in a variety of care settings. This system permits the clinician to build a computer-based problem-oriented patient record and to couple that record with knowledge derived from the literature.

Many authors have argued that an automated ambulatory medical record would improve care and provide diagnostic support (Jenkin, Cheezum, Essick, and others, 1978). Further, an automated record would improve productivity, accessibility, and accuracy. More specifically, the automated ambulatory medical record improves: (1) organization and reporting of patient information; (2) efficiency and accuracy of clinical decisionmaking; (3) guidance for future policies and practice; and (4) data retrieval and organization (McDonald and Tierney, 1988). The Institute of Medicine (IOM) is supporting the development of a computer-based medical record and has recently completed a study documenting its necessity (Dick and Steen, 1991).

In addition to practice benefits, AAMRSs can support health services and clinical research. They can be used for epidemiologic studies, risk analyses, drug surveillance, resource consumption and quality assurance analyses, and studies of variation in clinical delivery (Tierney and McDonald, 1991). With regard to the latter category, Roper, Winkenwerder, Hackbarth, and Krakauer (1988) and Ellwood (1988) recognized the need for systematically derived data with which to evaluate the effectiveness of medical care (Agency for Health Care Policy and Research [AHCPR], 1991).

Although the importance of automated medical records has been recognized and discussed for 25 years, automated ambulatory records systems are used in relatively few institutions (Shortliffe and Barnett, 1990). Automation in outpatient settings has focused on applications that are often tied to revenue and administrative tasks such as billing, claims submissions, scheduling, and registration. These applications are also less expensive than a medical records system. As of 1989, 71,000 vendors offered commercial ambulatory care information systems (Matson and McDougall, 1990).

Some authors (Mayo and Ball, 1988) identified an extensive list of features in office practice systems:

- Automated patient recall for followup.
- Medical records.
- Prepaid plan accounting and referral tracking.
- Medical/surgical knowledge bases.
- Computer-assisted instruction.
- Appointment scheduling.
- Patient care plan tracking.
- Utilization review.
- Management statistics.
- Claims submissions.

Few vendors, however, offer such a comprehensive range of products, and many do not seem to comprehend the need for AAMRSs (Dick and Steen, 1991; Matson and McDougall, 1990). The IOM conducted a survey of 12 vendors associated with clinical information systems. Findings indicate that vendors are generally pessimistic about physicians' and nurses' interest in entering data. Other vendor-identified impediments to the success of AAMRSs include the cost of the system and resistance to change in the health care industry. The need for interdepartmental sharing of information and the lack of standards to manage such sharing further decreases the likelihood of success (Dick and Steen, 1991). It is thought that the widespread use of well-documented and supported AAMRSs based on current technology will depend on commercial vendors.[1]

Barriers to Automated Ambulatory Medical Records Systems

Vendors and authors have pointed out barriers to AAMRSs. A frequently cited barrier is difficulty with the machine-person interface. For data to be accessible for retrieval, they must be structured rather than gathered in the free-form text that characterizes the familiar paper record. Until voice-recognition is perfected, many physicians will resist changing from their current practices to filling out structured forms. Another problem is the electronic collection of data from various services within a hospital or within the health care system, such as laboratories. If the interface involves two discrete

[1] Robert C. Sherrick, M.D., George Washington University, personal communication, September 1991.

applications within the same system, interface problems are minimal. If the interface is between two different hardware/software systems, however, it is problematic and still a challenge for systems engineers (Whiting-O'Keefe, Whiting, and Henke, 1988). Other barriers, mentioned in the past but not as relevant today, are the costs of data storage, which have decreased, and fear or discomfort with computers, which also has diminished as computers have become part of everyday life. Masys (1989), however, recently stated that the "fully electronic clinical record is a costly and elusive goal for most health care organizations because of technical, financial, and sociologic constraints."

Existing Automated Ambulatory Medical Records Systems

Although AAMRSs are not commonplace, they have been developed and implemented in academic settings in a number of institutions since the late 1960s and early 1970s. Several of these systems, such as TMR (The Medical Record) and COSTAR (Computer-Stored Ambulatory Record), were implemented either to replace the paper medical record because of mentioned difficulties in an outpatient setting or to become part of a hospital system. Several of the following systems were stimulated by funding from the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), the predecessor of AHCPR. These AAMRSs include COSTAR, originally at the Harvard Community Health Plan (HCHP) (Barnett, Justice, Somand, and others, 1979); TMR at Duke University Medical Center (Stead and Hammond, 1988); HELP (the Health Evaluation Through Logical Processing) at the Latter Day Saints Hospital in Salt Lake City; RMRS (the Regenstrief Medical Records System) at the University of Indiana Medical Center (McDonald, Tierney, Martin, and others, 1990); and the system at Beth Israel Hospital in Boston (Bleich, Beckley, Horowitz, and others, 1985). These systems were implemented about 20 years ago, have evolved as the technology has changed, house thousands of patient records with data collected longitudinally, support retrieval mechanisms, and have been the basis for clinical and outcomes studies. Their founders have become leaders in the medical informatics field and are insightful regarding the technical and pragmatic issues relating to the implementation of AAMRSs.

Often linked with this group is STOR (Summary Time-Oriented Record) at the University of California at San Francisco (UCSF) Medical Center (Whiting-O'Keefe, Whiting, and Henke, 1988) and THERESA at Grady Memorial Hospital, the teaching hospital for Emory University Medical Center (Walker, 1989). STOR and THERESA are more recent systems that have incorporated distributed and/or local area network (LAN) technology. These systems share common attributes including:

- Data dictionaries that store the names and characteristics of their data elements.
- Data collection over time that provides a longitudinal picture of the patient.
- Data retrieval capabilities to support patient care and research applications.
- Selective storage of information.
- Concern with data security.

With regard to selective storage of information, these AAMRSs do not contain all details that describe an observation but only keep clinically relevant information. The existing systems (described in Chapter 2 of this review) also differ in the following ways:

- The hardware and software on which they are built.
- The kinds of information they house.
- The vocabulary they use for storing information.
- The user interface (who enters the data).
- The type of prompts for clinical detail.
- Their record structure.
- Their inpatient or outpatient emphasis (McDonald and Tierney, 1988).

Another AAMRS that has been in operation since 1968 is PCIS (Patient Care Information System), which serves Alaska Natives and the Papago Indian Reservation in Tucson, Arizona (Levinson and Dambro, 1984). In addition to practice-oriented AAMRSs, automated clinical research systems have been developed that also capture ambulatory medical records. Of particular interest to this study of AAMRSs is ARAMIS, developed by Fries

and others at the Stanford University Medical Center in the early 1970s. The system was initiated on the premise that solutions to problems of chronic diseases require large data bases of high quality longitudinal data to support studies of disease progress and outcome (Shortliffe and Barnett, 1990). Although focused on arthritis and rheumatology, ARAMIS provides access to over 22,000 patients in 17 institutions.

Since the introduction of university-based automated medical records systems, systems have been developed that share many of the same characteristics as the original systems. These include outpatient systems under development or recently in prototype at Columbia-Presbyterian Medical Center (CPMS) (Shea, Clark, and Clayton, 1990); Brigham and Women's Hospital in Boston (Teich, Geisler, Cimerman, and others, 1990); Albany Medical Center in Albany (Ellis, 1990); Loyola University Medical Center in Chicago (Price, Chandrasekhar, and Tamirisa, 1990); and University of California at Los Angeles (UCLA) (Wilton, 1990). The Mayo Clinic is also in the process of automating its medical records (Pryor, Califf, Harrell, and others, 1985). In addition, there are provider-specific systems such as a family practice system using PARADOX and TORNADO (Davis, 1989).

Ambulatory health care units are increasingly being aggregated in large outpatient clinics, HMOs, and hospitals, and these medical records systems might be the appropriate focus of a combined data base. Individual practice systems are important, however, because of their practice patterns, even though their ability to participate in a national collaborative effort may be limited. Medical centers, HMOs, and other institutions using AAMRSs have research and technical staffs which support data retrieval efforts that individual practices do not have.

AAMRS systems also are in use in other countries such as DIOGENE in Geneva, Switzerland (Scherrer, Baud, Hochstrasser, and Ratib, 1990); BAZIS in The Netherlands (Safran, 1990); PEN&PAD, a physician workstation in England (Nowlan, Rector, Kay, and others, 1990); MEDSUM, a general practice medical record summary in Australia (Bridges-Webb, 1986); a system using Revelation, a personal computer data base management system, in Hong Kong (Chan, Donnan, Chan, and Chow, 1987); the Exmouth Project in England that uses Smart-Cards (Dick and Steen, 1991); and other systems in The Netherlands, Germany, and England. Lack of the ability to access data from foreign countries, however, may be a major barrier to considering them for an AAMRS data base.

Interstudy, under the direction of Paul Ellwood (1988), has an Outcomes Management System that includes survey instruments to describe patient demographics, functional status, treatment, lifestyle, insurance, and outcome. Participating HMOs and other health care organizations collect the data for quality assurance monitoring. This system may be a source of data for an AAMRS data base.

Large HMOs such as the Group Health Cooperative of Puget Sound in Seattle have pieces of an automated medical record system and are considering development of an integrated system. In the early 1980s, Kaiser Permanente had an integrated system under development, but efforts have been postponed because of funding (Levinson and Dambro, 1984). Recent communication with Kaiser staff indicates that although an integrated medical record system does not yet exist, there is hope that development plans will be reactivated. Lovelace Medical Center in Albuquerque, which has an HMO associated with the hospital as well as a research foundation, acknowledges the potential richness of HMO data bases and has implemented a Lovelace Patient Database to support clinical studies (Lapham, Montgomery, and Hoy, 1990).

Also to be considered are AAMRSs sponsored by the Federal Government. The Department of Veterans Affairs has a system called GRAMPS that supports geriatric outpatient practice (Hammond, Prather, Date, and King, 1990) and is considering the development of an AAMRS. The Department of Defense is implementing the Composite Health Care System (CHCS) at installations around the world (Dick and Steen, 1991). The Research and Patient Management System Center (RPMS) is used by the Indian Health Service to service Indian reservations.

Data Retrieval

The AAMRSs that have been in operation for a length of time such as TMR, COSTAR, HELP, RMRS, the Beth Israel System, STOR, and THERESA have retrieval capabilities that facilitate analysis of the housed data. Adams (1986) reviewed the query languages that support COSTAR, RMRS, and HELP and found that they allow nonprogrammers to retrieve data. It should

be noted that the application that Adams studied supported patient care rather than research. There are numerous studies that have been accomplished from these data systems, however, that indicate that the data can be transmitted to statistical packages for research studies.

Data quality. When an existing AAMRS is considered for research, the quality of the data must be reviewed (Gardiner, 1978). A recent study (Ellis, Krogh, and Werth, 1990) reported that when charts were compared with computer records, differences in over 47 percent of the diagnoses were found. It should be noted that the computerized records were housed in a billing system and not routinely used for care. Their analyses, however, showed that differences were attributed to: (1) informal and undocumented coding rules, or lack of guidelines; (2) software bugs; and (3) difficulty in medical coding. These issues must be addressed for AAMRSs as well.

A review of existing AAMRSs shows that all of the systems contain editing and logic modules which check relationships within and among data elements. It is clear that data quality is an important consideration for the existing systems and that within a system confidence in the data is high.

Data coding and standards. It has been argued that one of the benefits of an automated ambulatory medical record is the structure that it imposes on a nonstructured report. It also has been argued, however, that physicians resist structure and coding and prefer to report findings in the traditional narrative format. There have been some efforts to translate narrative reports into a structured medical record using linguistic analyses (Hirschman, Story, Marsh, and others, 1981), but this approach is not used widely. Instead, the existing AAMRSs use coded terms and data dictionaries of medical terms particular to each system. For data to be shared both within and across care settings, there must be standards for recording data (Medical ADP systems, 1991).

Numerous coding systems can be found in medical records generally and ambulatory medical records specifically. These include SNOP (Systematized Nomenclature of Pathology), ICD–9–CM (International Classification of Diseases, 9th Revision, Clinical Modification), CPT–4 (Current Procedural Terminology, 4th edition), SNOMED (Systematized Nomenclature of Medicine), MeSH (National Library of Medicine's medical subject headings, POR (Problem-Oriented Record), and DRGs (diagnosis-related groups). These coding systems are used for different purposes. The ICD–9–CM system is used for diagnoses and cause of death categorization, the CPT–4 for procedures categorization, and DRGs for reimbursement. There have been efforts to retrieve data using SNOP syntax (Dunham, Pacak, and Pratt, 1978) and to develop DRGs relevant to ambulatory care settings (Rogerson, Stimson, Simborg, and Charles, 1985).

Feinstein (1988) argued that a taxonomy of classification has three requirements: (1) suitable organizing principle, (2) labeled categories with standard titles, and (3) operational criteria for each member of a category. He pointed out that the ICD–9 contains few operational criteria, and that the POR may be useful for organizing information for a single patient but is idiosyncratic for research applications.

The IOM report (Dick and Steen, 1991) suggested that in order to develop a national computerized medical record data system, standards are required. Further, AHCPR (1991) noted that standard medical terminology is required for obtaining uniform clinical data for the Medical Treatment Effectiveness Program and other health services research.

Several efforts are underway to address the diverse coding systems. The American Society for Testing and Materials (ASTM) is working on the standardization of medical terminology (Gabrieli, 1990). The National Library of Medicine is undertaking the development of the Unified Medical Language System (UMLS) (Lindberg and Humphreys, 1990), which is designed to facilitate the retrieval and integration of information from many coding systems and sources of information such as literature, clinical records, medical data bases, and expert systems. It is establishing a conceptual link between the user's expression of an individual need and the relationship of information from various machine-readable sources through a metathesaurus. Columbia-Presbyterian Hospital is augmenting the UMLS project by attempting to translate and integrate the UMLS vocabulary with its local vocabulary (Cimino, Hripcsak, Johnson, and others, 1990). Other projects are developing vocabularies with systematic, modular linkages among terms (Rothwell and Cote, 1990).

Efforts also are underway in the United Kingdom and Europe to integrate terminology (Bernauer, 1990; Rector, Nowlan, and Kay, 1990;

Rossi-Mori, Thornton, and Gangemi, 1990). In addition, the Arden Syntax is being used to link information between the HELP and Regenstrief systems (Hripcsak, Clayton, Pryor, and others, 1990). Standard access to computer-based medical resources is also being approached through an interactive query workstation (Cimino and Barnett, 1990a). The latter two efforts may be applicable to the trans-data base communication that is required for an AAMRS data base.

Another related effort that may be relevant for an AAMRS is one that abstracts data from clinical and hospital data bases for research (Thompson, Piland, Hoy, and others, 1990). A structured approach was used, redundant data eliminated, and a relational data base formed. Although the approach worked, the authors argued that specifications of a minimum data set would be most useful for research.

Data Transmission Standards

The medical record is an assemblage of information from diverse sources such as laboratory, pharmacy, pathology, and radiology services. Although many of these ancillary services store information electronically, data are not available to the medical record because of the idiosyncratic representation of data, storage structures, diverse record identifiers, and unique coding structures. The lack of data compatibility applies within care settings and across care settings. These issues must be addressed in the development of standards for data transfer among computer systems (McDonald, 1990). Standards for data transfer specify the syntax of the message including content and format.

Several efforts are underway to develop standards for data transfer. In the United States, the ASTM, American College of Radiology and National Electrical Manufacturers Association (ACR/NEMA), the Institute of Electrical and Electronic Engineers (IEEE), and Health Level Seven (HL7) are implementing efforts to develop standards (AHCPR, 1991). HL7 is a consortium of vendors, users, and consultants that is developing interchange standards for all transactions in large medical institutions. It is in place in 40 sites, and these efforts are closely allied with ASTM. IEEE's project, the Medical Information Bus (MIB), seeks to give independent life to data. A workstation also is being used to provide a universal interface for hospital information systems (Shultz and Brown, 1989).

MEDIX (Medical Data Interchange) is a process by which regional groups of end-users and vendors develop inter- and intracenter communications through due process. IEEE's Pll75 is a MEDIX project (Harrington, Benson, and Spector, 1990). Efforts are also underway in The Netherlands regarding standards through the 3I and COPA projects (Branger and Duisterhout, 1990; Hasman, Arnou, Van Kesteren, and Ament, 1990).

As the AHCPR (1991) pointed out, development of standards is a first step in the process to incorporate standards into hardware and software systems, demonstrate the benefits, and gain widespread acceptance in the medical community. Data transmission standards are directly relevant to determining the feasibility of an aggregate AAMRS data base to support medical effectiveness research.

Implementation Issues

Issues with respect to clinical data base and AAMRS implementation are relevant to a collaborative ambulatory care data base as well. Issues include interface among the various systems within and across health care entities and the identification of a common core of data elements to be collected. McDonald (1990) and others have argued for clinical data interchange (CDI) standards. Another current issue is the development of standards for the patient computer-based record (PCR) (Detmer, 1990; Dick and Steen, 1991) and uniform medical languages (Lindberg and Humphreys, 1990). Issues of privacy and confidentiality as well as data quality continue to be of concern.

Barnett (1988) commented that training and documentation as well as technical support and programming competence are critical success factors. Pryor, Califf, Harrell, and others (1985) pointed out that clinical data bases depend on stable funding and a multidisciplinary team.

ARAMIS provides a model for a successful collaborative data base that can support medical effectiveness research efforts. Developers of clinical data bases stress several components of successful efforts (Kunitz, Fishman, and Gross, 1982; McShane, Haumann, and Glicksman, 1979; Pryor, Califf, Harrell, and others, 1985; Rosati, Lee, Califf, and others, 1982):

- Collaborative, multidisciplinary teams.
- Broad research questions that guide data collection and/or extraction.
- Software that facilitates retrieval and analysis.
- Ongoing quality control.

Numerous factors can influence the practicality, utility, and viability of an ambulatory care data base. Development and operational factors encompass collaboration and cooperation, technology, methodology, and costs. Additional operational factors include mode of maintenance, mechanism for support, and clinical site reimbursement.

Another area requiring collaboration is the identification or development of a method for data extraction and transmission to a central data base resource. Theoretically and practically, data do not need to be extracted with the same tool. Here again, the issue is that the same data be extracted across automated ambulatory medical records systems so that the clinical courses and outcomes of large numbers of patients can be studied. A related problem is that of maintaining patients' confidentiality. Individual clinical sites maintain name, address, and social security numbers as identifiers. A method for assigning patient numbers that are unique to the patient and follow the patient across treatment encounters is needed. This number must be maintained in the central data base so that data can be added to the correct patient record over time. Again, there are models from existing data bases that can be applied.

Funding and support for ongoing operation of a common data base are concerns that cut across clinical data bases. Development costs are circumscribed and have been paid for by Federal grants and contracts on numerous occasions. Operations and maintenance also have a history of Federal funding (for example, the Framingham Study, the Cancer SEER project, numerous long-term clinical trials). Clinical data bases per se, however, have not had a continuing source of funding (Ellwood, 1988). One of the feasibility tasks will be to estimate the costs for development, implementation, and operation of an ambulatory data base and to identify potential funding sources.

Conclusion

Some academic health centers have developed automated ambulatory medical records systems, and these systems provide a universe for potential aggregation. Although these systems are unique to each academic center, studies have been initiated to extract like data from a few of the systems.

Changes in the health care and reimbursement systems, technical advances, and interest in medical effectiveness research have caused numerous groups to explore the possibility of developing standards for a computerized medical record, to develop standard medical vocabularies and methods for translating among vocabularies, and to develop standards for data transmission. These efforts may be facilitated by the development of a central ambulatory data base, and conversely the implementation of a central data base may be facilitated by these developments.

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2. Medical Effectiveness and Health Services Research

Introduction

Health services research can be classified as methodological, descriptive, analytical, or experimental. Research can take place at two levels: the patient-provider level and the policy level (Brook, 1989). Patient-provider level research deals with the appropriateness or outcomes of care, and policy research may focus on levels of health care expenditures and equitable distribution of services. Models to relate the two are being developed.

Medical effectiveness research "investigates the effects of alternative treatments on outcome realized by the patient" (Agency for Health Care Policy and Research [AHCPR], 1991). Representatives of Government, private insurers, major corporations, community agencies, and the medical profession agree that in order to provide a basis for decisions on the future funding and organization of health care, it is essential to gain knowledge about variations in performance, relative costs, safety, and effectiveness through research (AHCPR, 1991).

Medical effectiveness research has been conducted by means of observational studies and controlled clinical trials, both of which have their shortcomings. In an observational study, normal clinical practice is recorded and outcome is compared among different procedures or treatments. Results may be biased, however, by systematic differences among patients receiving care. Often, observational studies (discussed in greater detail in Chapter 5: Methodological Issues) are retrospective and rely on secondary data obtained from heterogeneous sources.

In some cases, data used for medical effectiveness research are administrative in nature and include claims data and association-specific data (for example, the American Hospital Association). The amount of clinical data may not be sufficient to address the research questions. Severity, comorbidity, referral bias, or patient outcomes may not be detailed. The validity of the data and their completeness and accuracy are often unknown.

Controlled clinical trials involve carefully selected patients assigned to a treatment or procedure group. Because of the specificity of selected patients and interventions, however, the results may not be generalizable to a broader population.

Aspects of Medical Effectiveness Study

According to Berwick (1989), there are four key aspects in medical effectiveness research:

- The study of efficacy (knowing what could work).
- The study of appropriateness of care or effectiveness (using what works).
- The study of execution of care (performing care well).
- The study of the purposes of care (values that underlie action).

Berwick challenged the health care system to define the mission of health care in order to know which values guide the definition of efficacy, appropriateness, and quality. Although other authors would define or expand these aspects to include variations in care and outcomes, as well as other factors, there is general consensus as to the elements involved in health services research.

Efficacy

The definition of efficacy can include diagnostic efficacy to arrive at the correct diagnosis, management efficacy that reflects appropriate management practices, and prognostic or outcome efficacy to favorably improve patient outcomes (Pryor and Lee, 1991). Systematic evaluation of links that connect a patient's actual condition to the selection of a diagnostic test or treatment or a combination of these is essential to determining efficacy. This has not been carried out (Berwick, 1989; Brook and Lohr, 1985); however, technology assessment (Fineberg, 1985), decision analysis (Pauker and Kassirer, 1987), and randomized trials can contribute to this evaluation if researchers collaborate with statisticians, economists, computer scientists, and clinicians. Research in efficacy belongs at the highest level of aggregation through the Federal Government and professional and scientific organizations. The individual practitioner, however, must cooperate by sharing information and collaborating on the use of functional status measurements in routine practice (Nelson and Berwick, 1989).

Effectiveness of Medical Practice

Effectiveness, or the efficacy of medical interventions in actual practice, and the appropriateness of an intervention in a given setting are important concepts in health services research (Roper, Winkenwerder, Hackbarth, and Krakauer, 1988). Knowing the efficacy of a particular treatment or procedure does not translate directly into guiding medical practice because the realities of the health care world (for example, varying skills of providers) may affect the effectiveness or appropriateness of care. Therefore, efficacy and effectiveness research must go hand in hand. A way to routinely collect information about outcomes of tests, procedures, drugs, and other health care services would enhance knowledge about effectiveness. Study not only of services to patients but also of combinations of services or interactions of variables (for example, skill of physicians, region of country) may shed more light on the effectiveness of various treatments and the appropriateness of care (Brook and Lohr, 1985).

Guidelines to determine appropriateness of care have been proposed. A review of 4,500 hospital records showed that as many as 50 percent of the cases studied did not meet the criteria for appropriateness of care (Chassin, Kosecoff, Park, and others, 1987). For example, investigators found that one-sixth of patients undergoing coronary angiography and upper gastrointestinal endoscopy and one-third of those undergoing carotid endarterectomy had procedures deemed inappropriate by a panel of experts. Chassin (1988) suggested that guidelines for specific diagnostic tests or treatments that should or should not be performed in certain circumstances should be established. He, along with Brook at the RAND Corporation, used a panel of experts to arrive at a consensus about the appropriateness of various procedures and therapies (Nash, 1990). Eddy (1990a) suggested that the method used to develop practice guidelines should: (1) produce policies that are accurate and the outcomes they are supposed to produce; (2) be accountable, enabling others to review the reasoning behind the policy; (3) enable people to anticipate the health and financial consequences of applying the policy; (4) facilitate the resolution of conflicts across policies; and (5) facilitate the application of the policy both to individual patients and to populations. The outcome should determine the desirability of different interventions.

Efforts to establish guidelines for clinical practice have taken place in a variety of arenas. The Harvard Community Health Plan has developed guidelines for the care of common ambulatory conditions. However, more comprehensive data are needed to facilitate guideline development and enhance the credibility of guidelines. In 1990, RAND, the Academic Medical Center Consortium, and the American Medical Association agreed to establish a Clinical Appropriateness Initiative to "develop criteria, practice parameters, and other processes to identify and promote appropriate care..." (Berman, Kottke, and Ballard, 1990).

The Agency for Health Care Policy and Research has funded patient outcome research teams (PORTs) to study specific common conditions and the most effective treatments for them. These teams document the range of treatments available, examine variations in use of the treatments, establish probabilities for outcomes that are important to patients, and gain support and collaboration from providers (Wennberg, 1990).

The Health Care Financing Administration (HCFA) has been involved in a medical effectiveness initiative utilizing claims processing and peer review data to monitor trends and assess effectiveness of specific interventions. HCFA views assessment of medical effectiveness as involving monitoring, analysis of variation in practice patterns and outcomes, assessment of interventions, and feedback and education. Although HCFA data allow patient characteristics to be linked with treatment, the lack of clinical detail and specific information limits the utility of the data. In addition, Medicare and Medicaid data may not be representative of the general population (Roper, Winkenwerder, Hackbarth, and Krakauer, 1988).

Inherent in a discussion of effectiveness are the conceptually overlapping issues related to variations in care and outcome.

Variations in Care

Through the research of Wennberg (1985a, 1985b, 1991) and Wennberg, Freeman, and Culp (1987), systematic and persistent differences in the rates of use of medical care and common surgical procedures have been discerned. Using a methodology borrowed from epidemiology and known as small area analysis, Wennberg and colleagues proposed that variations in practice style can be attributed to two different causes (Wennberg, 1985b). First, controversies about efficacy and effectiveness

of alternative therapies cannot be resolved because the scientific information is inadequate. Low variation procedures are generally those for which there is professional consensus on diagnosis and preferred place or style of treatment. However, well-defined norms do not exist for many conditions—including those related to aging, hysterectomy, prostatectomy, coronary bypass, and others—and the Wennberg studies do not provide conclusions about which treatment produces a better outcome. Patient and provider data need to be linked with outcome measures to determine the effectiveness of treatment (Wennberg, Mulley, Hanley, and others, 1988). Therefore, treatment may depend on the experience of the physician. This becomes the basis for the second cause of variation in practice and is less likely related to scientific controversy. Physicians' choices of treatment may be motivated by their own or their patients' preferences or convenience or their perceptions of their need to protect themselves from liability (Barry, Mulley, Fowler, and Wennberg, 1988; Friedman, 1986).

Eddy (1984) agrees that uncertainty exists in physicians' information processing, history taking, symptom observation, and diagnosis. A study of these aspects of clinical practice is necessary to design better guidelines for treatment and care. Wennberg (1985b) labeled these differences the "practice style factors" and noted their effect on medical effectiveness research and cost containment. For example, differences in the need for hospitalization are the most important determinant in per capita costs of treatment for specific diseases. The decision to treat in an ambulatory setting versus an inpatient setting affects the resources needed and has profound implications for the patient and the payer. Differences are worldwide and are not explained by the incentive associated with fee-for-service medicine.

A wide variety of studies on variations in care exist. For example, a review of the use of respiratory therapy at a Massachusetts hospital found it far exceeded the state-wide average (Zibrak, Rossetti, and Wood, 1986). When advised about the optimal use of various respiratory therapy options by trained respiratory therapists, physicians decreased their use of respiratory therapy with no effect on morbidity and mortality from pulmonary disorders. In two other studies, differences in hospitalization rates of internists and family physicians were examined. One study (Franks and Dickinson, 1986) found no interspecialty differences in length of stay, hospital charges, number of procedures done, or disposition. Family physicians, however, recorded fewer diagnoses than did internists. The second study, using the MedisGroups comparative data base, compared outcome measures in hospitalized patients over age 65 treated by internists and family physicians (McGann and Bowman, 1990). According to this study, patients admitted by family physicians had a significantly higher admission illness severity and were significantly older; however, there were no differences in morbidity and mortality. The lower charges for patients admitted by family physicians were statistically significant and reflected variation in the use of diagnostic tests and procedures. In still another study describing the extent of variability in diagnosis and treatment of temporomandibular disorders, the authors noted that the differences were not related solely to patient-reported pain and dysfunction (Von Korff, Howard, Truelove, and others, 1988). The results indicate the need for systematic approaches to identifying, evaluating, and modifying variations in health care practice.

Dittus and Tierney (1987), using Regenstrief data, examined variation in how often physicians see outpatients for followup visits. They found a four-fold difference in return visit intervals between the longest and shortest intervals for followup. Differences could not be accounted for by patients' diagnosis or clinical status. In addition, physicians with the shortest followup interval ordered more diagnostic tests.

Wennberg and colleagues, in responding to their and others' observations of variations in care, suggested that compiling and distributing reports detailing per capita use rates for specific health care markets will assist in addressing variations in care (Wennberg, Freeman, and Culp, 1987). These reports would need to be based on systematically collected, accurate data that are available across market areas. Health information about total populations would enable better decisionmaking and planning in the health care field (Wennberg and Gittelsohn, 1973). Closer monitoring of medical practice could obtain population-based measures of resource allocation, service use, and outcomes of care. Health insurance records (Medicare, private insurers) and hospital discharge abstracts contain information on hospital resources used. Discharge and claims records establish the link between use of medical care, diagnosis, and outcome. Hospital

outpatient data, emergency room data, and physicians' office data would present a view of the use of ambulatory care. Geographic location and organization of the health care community may influence resource allocation and service use rates.

The Wennberg reports would aid in addressing the effectiveness of common therapeutic interventions. The feedback of findings on practice variations and outcomes to State medical associations, specialty societies, and individual providers would enable them to reconsider indications for specific services and reduce the variation in practice patterns. Cost containment could be achieved by guidelines addressing the use of outpatient, ambulatory services in place of inpatient care. Reduction in hospitalization should not negatively affect the patient-physician relationship nor should it have a negative economic impact on physicians. Although this approach may raise concern about the effect on outcome, little or no information exists to confirm this fear. In a study comparing use of hospital beds in New Haven and Boston, Wennberg, Freeman, and Culp (1987) found no discernible difference in outcome but did find a great difference in hospitalization rates for conditions for which hospital admission is discretionary (for example, back problems, gastroenteritis, simple pneumonia). In a similar study (Perrin, Homer, Berwick, and others, 1989), hospitalization rates for children in Boston, Rochester, and New Haven were shown to vary greatly. No medical reasons for variations were proven, but socioeconomic status and access to primary care may have contributed to differences. The implications for cost and quality of care are obvious.

In Great Britain, a number of evaluation techniques and cost benefit studies have been implemented to assist in decisions about the relative benefits of various interventions in the treatment of cardiovascular conditions. The decision as to whether costs are worthwhile (that is, different use of technology or other interventions enhances outcome) will be included in the choice of the intervention (O'Brien and Rushby, 1990).

Another aspect of variation in care addresses the provider of care. Data drawn from the Columbia Medical Plan were used to evaluate the relative cost benefit of physicians and nurse practitioners in a pediatric setting (Salkever, Skinner, Steinwachs, and Katz, 1982). Results indicated that although nurse practitioners are less costly than physicians in providing care, they are not less effective.

Outcome Measures

Well-defined and reliable outcome measures allow researchers to study disease natural history, clinical course, and/or the effects of treatment interventions on similar groups of patients. In recent years, there has been an increase in the range of available outcome measures. Until the 1970s, most clinical studies defined outcome as a dichotomous variable, "dead" or "alive." New and better treatments, increased longevity of the population, and a growing focus on chronic disease created the need for more encompassing measures of outcome. Improved technology yielding a choice of treatments, increased competition among health providers, and increased consumer awareness have resulted in the need to include patient satisfaction and quality of life as outcome dimensions. Financial constraints have influenced the inclusion of efficiency and cost-effectiveness. The interest in the past 5 years on quality of care and quality assurance has also led to an increased interest in outcome.

Outcome measurement is a fertile area of research with much discussion as to the domains encompassed, mechanisms for measurement, mode of administration (health care practitioner or self), and the measures. Also actively debated is whether there should be a global outcome measure or disease- and/or age-specific measures.

In an effort to give patients, providers, and reimbursers better insight into making care-related choices and decreasing variations in care, Ellwood (1988) proposed an outcomes management approach to care. In the Shattuck lecture, he suggested that a national data base containing information on clinical, financial, and health outcomes be built so that the relationship between medical interventions, health outcomes, and costs can be estimated. Wennberg (1985b) suggested that a plan be designed and implemented to explain whether a specific intervention to treat a particular condition with a known level of morbidity gets a better result than another treatment.

Outcomes management would place greater reliance on guidelines and standards for use of interventions, measure the functioning and well-being of patients, pool clinical and outcome data on a large scale, and analyze and disseminate results into practice. It would, among other things, generate an understanding of the variations in practice style among providers in different geographic locations.

Research on outcomes is important in studies of the effectiveness of medical practice and may increase the efficiency of monitoring care (Epstein, 1990). For the majority of patients, outcome measures related to reduction of symptoms, improvement in daily functioning, or improvement in a sense of well-being and health-related quality of life are more appropriate than death as an outcome (Greenfield, Kaplan, and Ware, 1985). Methods used in outcomes research allow for heterogeneity in patients. Case mix adjustment separates the effects of care from those of preexisting health status and other influencing factors. Many attempts are being made to develop a severity of illness index (Horn and Horn, 1986; Iezzoni, 1990), distinguish costs due to severity differences across patients, and assist in identifying issues related to quality of care and outcome (Iezzoni, 1990). According to a study of mortality from transurethral resection of the prostate, case mix does not explain the difference in outcome through its influence on the choice of treatment (Roos, Wennberg, Malenka, and others, 1989). Further research in this area is needed.

There is interest in measures of physical and mental health, social and role functioning, and other general health concepts to be used in evaluating outcome. To be useful, these measures should address a variety of health concepts and health states and should adhere to standards of reliability and validity (Stewart, Hays, and Ware, 1988).

A variety of approaches to measuring functional outcomes have been developed and are being refined. The Sickness Impact Profile and the Index of Well-being are sound psychometric measures. The McMaster Health Index Questionnaire, the Duke-University of North Carolina Health Profile (Parkerson, Broadhead, and Tse, 1990), and the RAND Health Insurance Experiment (HIE) (Brook, Kamberg, Lohr, and others, 1990) provide accurate measures of outcome. Further research is needed to determine the practicality of these instruments for use in clinical settings.

Other surveys have been developed based on a few single-item measures. For example, Spitzer, Dobson, Hall, and others (1981) developed a quality-of-life index that aggregates five single-item measures of health and health-related concepts in a questionnaire that takes 1 minute to administer. However, single-item measures often are less reliable and less valid than longer measures (Stewart, Hays, and Ware, 1988). As a compromise between long and short instruments, Stewart and her colleagues developed a general, short health survey of function and well-being that is reliable, self-administered, and comprehensive. Roles, social interactions, physical function, emotions, and perceptions of health and pain are addressed in a 5-minute questionnaire.

The Medical Outcome Study (MOS) was designed to determine whether variations in patient outcomes are explained by differences in the system of care, clinician specialty, or clinician technical or interpersonal style and to develop a more practical tool for monitoring patient outcomes in medical practice. The MOS was implemented in Boston, Chicago, and Los Angeles in areas where a large health maintenance organization (HMO) and physician specialty groups were willing to participate in the study. Information about patient case mix, variation in technical and interpersonal style of practice, patient and provider characteristics, patient function, and other outcomes was collected. Not all of this information is generally noted in medical records, claims forms, or other available sources. Data collection from clinicians, patients, medical records, and independent clinical examination was undertaken (Tarlov, Ware, Greenfield, and others, 1989). Ware's (1991) interest in the patient's perspective on outcome of medical care led him to combine traditional clinical measures of disease status with the patient's view of disease and treatment. He suggested that it is not possible to move from efficacy research to effectiveness research unless new tools to define effectiveness include quality of life, function, and well-being from the patient's perspective. Existing data bases do not include the patient's experience of health care and health outcome, and therefore, new data bases need to be developed.

Today's technology allows storage and linkage of numerous patient descriptors with outcome and provides the opportunity to develop and assess more comprehensive, sensitive, cost- and time-effective measures. The large numbers of patients in a data base and the capability of analyzing multiple independent and dependent variables should aid in focusing on those measures that are reliable and most adequately describe outcome. Studies of outcome can be enhanced and models refined with an ambulatory care research resource that can link symptoms, treatment, followup, and measures of outcome.

Quality of Care

The study of the execution of care or quality of care is integral to effectiveness, variations in care, and outcomes. Computerized medical records have improved the ability to carry out quality of care research with large numbers of patient records. Although the tools for assessing quality of care have been developed over the years, they have not been integrated into larger models of health care delivery that would enable researchers to understand the meaning of variations in the use of services or to identify acceptable ranges of effectiveness.

In 1986, HCFA released a public report on hospital-specific death rates of Medicare inpatients in more than 5,500 American hospitals to reflect quality of care in those facilities. Although HCFA attempted to define a multivariate case mix model so that severity of illness could be accounted for, it has been criticized for publishing misleading data. Although death rates could reflect quality of care, assumptions inherent in the model were questioned (Berwick and Wald, 1990). Other studies (Hannan, Bernard, O'Donnell, and Kilburn, 1989) also attempted to target quality of care problems by reviewing mortality data. At the very least, interest in understanding variations in quality of care has been raised by the HCFA study. In a review of literature on differences in hospital mortality, Fink, Yano, and Brook (1989) noted that hospital mortality data were not gathered uniformly, were collected for only a short time, and often came only from local hospitals. Inability to measure differences in patients was a common concern of the authors of these articles. Recommendations to improve studies included acquiring longitudinal, prospective data from a variety of facilities in different geographical locations and developing strategies for translating the results into more effective practices.

Concern for quality of care in the ambulatory setting has grown as increasingly more care is being provided there. In addition, there is less peer review or quality assurance in ambulatory settings than in inpatient settings. According to Brook, Kamberg, Lohr, and others (1990), most studies of the quality of ambulatory care have been narrowly focused, examined one disease, or involved patients from a single institution or geographical area. In general, data in each study came from a single source such as insurance claims forms or medical records. Most studies examined either the process of care or the outcomes of care, but not both. When outcome was assessed, it was for 1 year or less. In many cases, the population-based studies were performed many years ago. The study by Brook and colleagues (1990) of the quality of care rendered in an ambulatory care setting for 17 common chronic conditions was based on data obtained from the RAND HIE. Quality of care was measured by process and outcome criteria to enhance the results of the study. Other researchers (Fries, 1983a) found that although process assessments yield the "hard data," such as laboratory results, outcome data reflect quality of life and well-being. In the Brook (1990) study, outcomes dealt with physiological measures and/or the effect of the condition on the patient. Process criteria included the appropriate use of visits and diagnostic tests or the appropriateness of the interventions. Data were obtained from insurance claims, screening physical examinations at the beginning and end of the study, and patient surveys from patients in six U.S. sites who were randomly assigned to insurance plans that were free or required cost sharing, or in one site, to an HMO. No data were collected from medical records. Physiologic outcome standards were shown to have been met 80 percent of the time. Standards for the effect of the condition on the patient were found to be met 80 percent of the time. Process of care standards were met less frequently than were outcomes criteria (55 percent). According to Brook and coauthors, there seems to be more room for improvement in process of care than in outcomes of care in this population with chronic conditions. This position, however, assumes that a direct relationship exists between process and outcome and does not address the relative worth in dollar costs of improving the process to improve the outcome. As a result of these findings, Brook and colleagues (1990) recommend additional work to link process and outcome models of the treatment of ambulatory chronic conditions so that quality assessment focuses on improving process, and therefore, outcome with no unnecessary increase in the costs of care. Other researchers do not necessarily agree with this approach. Equally important, this study demonstrated the type of research possible when there is access to large amounts of longitudinal data that can address issues of outcome and quality of care.

Summary

Medical effectiveness research on efficacy, effectiveness, appropriateness, and outcome, as well as variations in care and the quality of care, requires data on the setting where medical care is delivered, providers giving care, differences among patients, and the process and outcomes of care (AHCPR, 1990). The level of detail needed to address these areas is not likely to be found in existing secondary data sources nor in clinical trial data. Primary data collection can provide more complete information on a patient at a given time and over time. Linking of these records will increase the number of individual records available for study and enhance the generalizability of the results. The use of existing automated ambulatory medical records systems is one mechanism for utilizing primary clinical data in a cost and time-effective manner.

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3. Decisionmaking

Introduction

In the process of making a clinical decision, a physician is faced with several possible alternatives that must be weighed before the physician makes a decision (Dannenberg, Shapiro, and Fries, 1979). According to Dawson and Connors (1990), physician decisionmaking is influenced by the following factors: (1) information about diagnosis, prognosis, treatment alternatives, and patient preferences; and (2) physician-specific characteristics, such as personality, decisionmaking style, biases, confidence, personal preferences, and external pressures. To make accurate decisions, it is essential to have accurate data, pertinent knowledge, and appropriate problem-solving skills (Shortliffe and Perreault, 1990).

The Decisionmaking Process

The clinical decisionmaking process involves the estimation and comparison of possible alternatives with the outcomes of each of these generated alternatives (Dannenberg, Shapiro, and Fries, 1979). The first part of this process is a "question of facts" and deals with data collection and analysis. The second part is a "question of personal values or preferences," consisting of the comparisons between the potential benefits and harms of a given practice, the health outcomes associated with a given practice and its related costs, and the benefit gained for each of the possible practices (Eddy, 1990b). During this process, misperceptions of the outcomes or of the values that patients place on the outcomes may result in flawed decisions. The computer can be used to make decisions about diagnosis and process of care. Process of care may include knowing what questions to ask, tests to perform, and procedures to carry out. It also may include determination of the value of the results based on risks to the patient and financial costs.

Feinstein, Rubinstein, and Ramshaw (1972) suggested that the decisionmaking process is hindered by the following problems: (1) limited physician experience, (2) lack of direct access to a population of sufficient size for the purpose of properly matching patient conditions, and (3) the decisionmaker's inability to accurately estimate therapeutic outcomes. As a result, these authors advocated the implementation of a computer program that facilitates the physician's estimation of outcomes by providing access to a large data base of clinical experience and information. Computers, then, can be valuable assets in decision support as tools for information management, focusing attention, and specific patient data (Shortliffe and Perreault, 1990).

According to Mutschler (1990), decision support systems are directed at unstructured problems, use decisionmaking models and analytic techniques, and attempt to enhance the effectiveness of the decisionmaking process without supplanting the role of the decisionmaker. Using a large and complex data base enables the physician, with the aid of a decision support system, to consider diagnoses, prognoses, and/or treatments that otherwise might have been overlooked or inappropriately discarded. In fact, one study suggested that failure to make a correct decision may be due to the failure of the physician to generate a comprehensive list of diagnostic possibilities that not only contains the correct diagnosis but includes only the more likely ones (Barnett, Cimino, Hupp, and Hoffer, 1987; White, 1985).

To obtain such a list, the physician first must record the necessary patient information which, for optimum efficiency, should have diagnostic significance and the greatest potential for reducing the set of possible diagnoses. In generating this list, the user must define each observation correctly because the inappropriate use of medical terms or inaccurate recording of physician observations will most likely result in incorrect assessment of the patient's condition (Dietrich, 1978).

Decision Support Systems

The various types of clinical decisionmaking systems can be characterized by their attributes. The system function may enable the computer to produce facts about the patient (diagnosis) or may suggest what to do for the patient (process of care). The mode of giving advice may include identification of the diagnosis and the capacity to respond to

the providers' inquiries about the process of caring for a patient with that diagnosis, or it may automatically give the provider the options for care. The consultation style may generate advice for the provider about diagnosis and/or management, or it may utilize a critiquing style in which the computer responds to the providers' suggestions for care by agreeing or disagreeing. The underlying decision science methodology may range from simple logic to more sophisticated Bayesian statistics, decision analysis, artificial intelligence, or a combination of these. The human-computer interface characteristics include logistical considerations of access and ease of use, mechanical considerations such as types of data entry (keyboard, mouse, touch screens), and psychological considerations. The combination of these characteristics may determine the utility of the computer and its acceptability by health care providers (Shortliffe and Perreault, 1990).

Decision support systems have been created for such areas as glaucoma (Weiss, Kulikowski, and Safir, 1978), lung cancer (Feinstein, Rubinstein, and Ramshaw, 1972), endocrinology (Schild, Lunenfeld, and Gavish, 1978), cardiology (Nomura, 1974), and radiology (Dietrich, 1978). The glaucoma consultation system, for example, incorporated a network of medical knowledge necessary for reasoning and decisionmaking processes (Weiss, Kulikowski, and Safir, 1978). In simulating the physician's own diagnostic process, the interactive system proposed by Schild, Lunenfeld, and Gavish (1978) prompts the physician for relevant patient data to ensure that the amount of information requested is minimal.

Conclusion

Although Barnett, Cimino, Hupp, and Hoffer (1987) stated that information systems provided better access to knowledge bases than did textbooks or journal articles, they also identified some problems hindering the effect of such systems on the physician decisionmaking process: (1) difficulty in obtaining access and interacting with the systems, (2) limited coverage of diseases and conditions in the systems, (3) limited ability of the decision support system to explain and justify its interpretations, and (4) poor quality of these interpretations. Regardless of these limitations, Dannenberg, Shapiro, and Fries (1979) found that computer-generated prognoses resulted in an improved ability for physicians to predict therapeutic outcomes.

There is a dearth of information in the literature related to immediate access to data bases that would enable clinical decisionmaking. Issues related to making collected data available in a timely manner are key to enhancing the use of computer-based decisionmaking in clinical practice.

Implementation of automated ambulatory medical records systems in clinical practice not only improves the physician's ability to process information and record medical history and observations of symptoms but also results in better feedback concerning treatment outcomes and enhances physician decisionmaking ability. Furthermore, a continuously growing standardized data base of medical information, practices, and outcomes will facilitate medical effectiveness research.

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4. Legal, Confidentiality, and Privacy Issues

Introduction

Computer-based patient records bring into play a variety of laws that focus on controls on the privacy and confidentiality of information contained in the records. The key legal issues related to computer-based patient records include regulatory and accreditation issues, evidentiary issues, patient privacy and record access concerns, record ownership questions, and legal risks specific to computer-based patient record systems.

Regulatory and Accreditation Issues

The statutes and regulations governing health care records are concerned with the creation, authentication, retention, storage, and media for storage of patient records. In addition, State regulations provide for confidentiality, record content, accuracy, completeness, timeliness, and accessibility of medical records (Dick and Steen, 1991). The antiquated licensing laws make computerized medical records technically illegal in 12 States and legally ambiguous in 16 others (Gardner, 1991b). The laws are outdated, inconsistent, and difficult to interpret. The wide variance in requirements for medical records will make it difficult to develop patient record systems that comply with laws in all 50 States. Most laws reflect concerns about the legal acceptability of the computerized medical record as a substitute for the handwritten one (Roach, Chernoff, and Esley, 1985). California and Maryland have comprehensive medical record statutes, and Montana and Washington have adopted the Uniform Health Care Information Act.

States determine the minimum requirements for the content of medical records. The amount of personal, financial, social, and medical data contained in the medical record varies by State. In general, States require the patient's consent to disclose the contents of the medical record, and the specifics are State-determined. Rhode Island permits disclosure, with certain restrictions, without patient consent (Supplement of Rhode Island General Laws), and Wisconsin allows limited disclosure of information in the medical record without patient consent for researchers affiliated with the provider (Glenney, 1989). In North Carolina, the patient may waive this privilege (Gellman, 1984).

Traditionally, the physician's signature authenticated the medical record, and some States still require it. Other States permit electronic signatures or the use of a computer key word. In Oklahoma, physicians may use a computer key to sign medical records but must use a pen to order medications, procedures, or tests (Gardner, 1991b). In Oregon, the physician may sign orders with any "unique identifier" including fingerprints. South Carolina permits the use of a signature stamp with "appropriate controls" (S.C. Standards for Licensing Hospitals and Institutional General Infirmaries 601.6, 1990); Iowa requires medical records to be "written" and "signed" by the physician (Iowa Administrative Code 641.51.5, 1988).

Laws governing the media for storage and the manner of storing medical records exist in many States and relate, in part, to what constitutes admissible evidence in court. For example, in Texas, Mississippi, Wisconsin, and New Mexico, medical records must be stored in the original (paper copy) or on microfilm (Gardner, 1991b). In some States, the hard copy printout becomes the original physical record and is part of the patient medical record. Data stored on tapes must be made visually intelligible and turned into written form (Tomes, 1990). In all States, provisions must be made for record security to protect confidentiality and to prevent alteration or falsification of the record. Few States have laws for altering medical records; those that have such laws require that both the original record and the changes be available.

Personnel security, physical security, and system security, including rules about access, must be assured. Only authorized users can have access to portions of the records that are relevant to their particular function. States vary on who can authorize the use of a medical record. Patients, parents of minors, Institutional Review Boards, the State, and others may have the right to authorize release of the record. However, who may authorize and when and how authorization can take place are subject to

variability and may be unclear. Access to sensitive records, such as those relating to acquired immunodeficiency syndrome (AIDS) or drug and alcohol abuse information, should be particularly well controlled. This is provided for in the Privacy Protection Act for federally held data. Policies regarding written records require that medical records be kept on the premises of the care provider. How this affects computer storage of records at remote sites, for example, in shared facilities that reduce cost of storage, is unclear. It appears that as long as the patient's privacy is protected, off-site storage is permissible (Gardner, 1991c).

The length of time a record must be kept varies from 5 years to permanently, with most States requiring retention for 5 years (Roach, Chernoff, and Esley, 1985). Record ownership also is State-determined, with most States agreeing that the facility or provider owns the data, subject to the patient's interest in the information contained in the record. Disclosure of medical records for utilization review and quality assurance is allowed by the State and is mandated by the Federal Government for any federally funded providers (American Medical Record Association, 1985). In Quebec, joint ownership of the medical record by the patient and the provider is provided for by law (Briere, 1990).

Use of Medical Records for Research and Quality Assurance

The use of medical records for research by medical and nursing staff who are part of the institution collecting data and the use of medical records for utilization review and quality assurance may depend on the patient's informed consent, but such use is becoming more acceptable in most States, even without consent (Gordis and Gold, 1980). A discussion of the physician's obligation to protect privacy (Gellman, 1984) noted that the American Medical Association does not address the use of medical records for research and therefore the State, in this case North Carolina, must do so.

Many attempts have been made to clarify the issues associated with the use of medical records for research and quality assurance. Federal safeguards for the use of medical information for research are reflected in the Privacy Protection Study Commission (1977) report. Data held by Federal agencies concerning identifiable individuals may be released without subject consent based on interagency need to know, for statistical records, and for routine use reflecting a purpose compatible with purposes for which the data were collected. Specific data protection is provided by a variety of Federal agencies, including the Agency for Health Care Policy and Research (AHCPR), the Department of Veterans Affairs, all Federal agencies that hold drug and alcohol abuse treatment data, Peer Review Organizations, and others. An attempt to allow disclosure of records without patient consent was unsuccessful. The American Medical Records Association (1985) prepared a position paper proposing the release of medical records for research without patient consent under specified conditions, including review by an Institutional Review Board. The American Statistical Association's Ad Hoc Committee on Privacy and Confidentiality (1977) suggested that records be transferred among agencies for statistical and research purposes as long as confidentiality of data is protected and a public purpose is served by the data transfer.

Several organizations have been investigating the legal, policy, and ethical issues associated with researcher access to patient records. The Committee on National Statistics and Social Science Research Council, Panel on Confidentiality and Data Access, will study the data collection activities on individuals and establishments related to surveys, administrative record data, and epidemiological studies. The Department of Health and Human Services Task Force on the Privacy of Private Sector Health Records, of which AHCPR is a part, is examining the extent to which there is a problem regarding the use of personally identifiable health records. The American Public Health Association Record Linkage Work Group is examining a variety of public health research and other issues related to data linkage (AHCPR, 1991).

In Great Britain, the Medical Research Council (1973, 1985, as cited in Waller, 1991) upheld the use of medical records without the patient's explicit consent as long as confidentiality was maintained. Canada, too, protects the confidentiality of the patient while allowing release of medical records for research with the patient's consent.

In summary, there is general acceptance of the use of medical records for research and quality assurance. However, there does not appear to be agreement on whether the patient must consent to its use. In all cases, it is assumed that patient confidentiality will be maintained and that reasons for

use are justified. This allows for wide latitude in the use of medical record information.

Inherent in the ability to use medical records for research or quality assurance is the need for record linkage. The American Public Health Association's Record Linkage Work Group is examining the issues related to linkage including: confidentiality protection in Federal, State, and private sector arenas; the effect of confidentiality on provider reporting; ownership of linked files and their subsequent use; and the use of individual identifiers, scrambled identifiers, or data stripped of identifiers.

Patients' rights. The Federal Privacy Act (Health Care Financing Administration, 1974), supported by similar acts in many States, provided assurance that patient records held by the Federal and State Governments will not be disclosed to third parties without the patient's consent, except under specific conditions (U.S.C. 552a). A wide variety of statutes govern patients' rights, and many State laws neither cover nor exclude records held in the private sector. There is an increasing demand for information about the social, financial, demographic, and medical data contained in the medical record. In addition to peer review bodies, third-party payers, outside billing and computer services, employers, insurers, and others who use health care information for non-health-care purposes want access to the medical record (Waller, 1991).

Computerization of medical records makes it difficult to control the redisclosure of data to other parties and the abuses inherent in the uncontrolled use of that information. Information that crosses State lines will not be subject to the same constraints held within the originating State. As patients and providers become more aware of the potential for misuse of medical record information, the medical record itself may be compromised. Professionals and patients may be unwilling to provide complete or accurate information about sensitive issues such as AIDS, psychiatric problems, or alcohol and drug abuse (Burnum, 1989).

Privacy and confidentiality issues are of great concern in anticipating the use of automated medical records. Computers increase the amount of information collected (Gellman, 1984), the number of people who have access to the data, and the degree to which the data are shared and exchanged (Andreoli and Musser, 1985; Goldman, 1987). Privacy is defined as the right of an individual to control the amount of information he divulges about himself. Confidentiality describes how the information, once collected, will be treated (Trute and Tonn, 1982). To protect privacy and confidentiality, it is necessary to:

1. Separate data sufficiently from individual identifiers and to aggregate data sufficiently when reporting on them to avoid inadvertent disclosure of information.
2. Limit the collection of data to necessary items only.
3. Provide for security of the computer systems.
4. Permit access to data only on a "need to know" basis.

Although each State supports the individual's right to privacy and confidentiality, the individual is not well protected. The Uniform Health Care Information Act (National Conference of Commissioners on Uniform State Laws, 1985) detailed the manner in which patient information may be released. Only Montana (M.C.A. 50–16–501) and Washington (as of July 1991) have enacted this into law (Andreoli and Musser, 1985). Providers are obligated by State licensure laws and statutes to maintain the confidentiality of patient records and protect them from unauthorized release whether they are maintained on paper or computer. As described earlier, however, it is much more difficult to protect and control access to computer records.

Patients always have access to portions of the hospital record that contain their data, but their right of access to records held by physicians and other individual providers is not as clear. Access is generally granted in response to a written request; however, only a summary of the medical record may be made available. Again, who grants authorization and under what conditions and to whom it is granted is variable and often unclear. Providers may prevent patient access to psychiatric records but provide those records to an appointed representative. Patients may not even know about the existence of insurers' and others' data bases and therefore not be able to enforce their right to access. In addition, once access is gained, the patient may not have the right to correct inaccuracies in the record. These restrictions on the patient's right to access may limit his or her willingness to support an automated medical record.

Providers' rights. The provider, whether institutional or individual, may have concerns about the privacy and confidentiality of the medical record—for example, they may be concerned that increasing access by patients and others to the medical record will lead to increased litigation related to practice patterns and patient outcomes. They are likely to be concerned, too, about the security of the records and the chance for falsification or abuse of their contents. Improper aggregation of data and/or failure to separate identifying information from other data could lead to inadvertent disclosure of the provider's identity.

Security policies and confidentiality. Security of automated medical records has been addressed by many of those who have implemented automated ambulatory medical records systems. These security measures focus on passwords, authorized access, and levels of access. For example, someone may have read-only access to the data, or there may be usage monitoring and warnings regarding unauthorized use.

In the University of Pittsburgh (Presbyterian Hospital) system, initial policies that required dial-back security were unworkable. The System Security Study Committee suggested several steps for computer system security (National Research Council, 1991):

- Promulgation of a comprehensive set of Generally Accepted System Security Principles (GASSP).
- A set of short-term actions for system vendors and users that builds on readily available capabilities and would yield immediate benefits.
- A system-incident data repository and appropriate education and training programs to promote public awareness.
- Clarification of export control criteria and procedures for secure or trusted systems and review for possible relaxation of controls on the export of implementations of the Data Encryption Standard (DES).
- Funding and directions for a comprehensive program of research.
- A new organization to nurture the development, commercialization, and proper use of trust technology, referred to as the Information Security Foundation, or ISF.

Evidentiary Issues

Computerized medical records can be structured to be admissible as evidence in court in disputes between providers and patients or payers. Computer-based records are considered to be hearsay evidence unless one of the many exceptions apply. For example, if computer records are kept regularly in the ordinary course of care, they can be admitted as evidence in court. In addition, the original record must be maintained, each person who makes an entry or modifies a record must be identified, and the changes to the record also must be identified (Waller, 1991).

Liability Issues

Computer programs are considered to be products because they are owned, exist through time, may have errors that can be corrected, and can be passed from one person to another. They are therefore subject to strict liability. The computer can produce information which the provider accepts without verification, such as laboratory results, and the program can be liable for errors. A defect in a computer system that results in logic errors or programming errors can cause liability. Systems most likely to be involved in litigation include patient record and treatment support systems because they contain many different types of information, operate in real time, and utilize remote terminals (Brannigan, 1989).

Summary

Confidence in the ability to protect privacy and confidentiality will reduce the fear of computers for patients and providers (Bank and Laska, 1978). Patient rights, provider rights, and evidentiary and liability concerns will be addressed by ensuring that inadvertent disclosure of the contents of the medical record will not occur and that the contents will not be altered. Uniform national standards for computer-based records and record systems need to define creation, authentication, storage, and retention of patient records. Adoption of a Uniform Health Care Information Act would provide patients access to their health records, the ability to correct information, and the guarantee of confidentiality across State lines. It would define the rights and obligations of third parties who receive the information and prevent disclosure or abuse of patient information. These issues will need to be considered in the development of an automated ambulatory medical records data base to support medical effectiveness research.

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5. Methodological Issues

Introduction

Available data bases may contain useful data on ambulatory care: insurance claims data bases, randomized clinical trial (RCT) data bases, intramural research data bases, administrative or health care management data bases, clinical data bases, and quality review data bases. Despite their differences, these data bases can be used to generalize from the individual to the patient population. The utility of each is based on the degree to which this generalizability is possible. The data base's structure, accessibility, quality, and the manner in which the data are stored all contribute to its use. Combining data from data bases to address issues of interest requires consistent definition of data items and quality data (Muhlbaier and Pryor, 1989).

Of the potential sources of data on ambulatory care for the study of medical effectiveness, two have emerged from existing research studies—clinical trials and clinical data bases derived from observational studies. Clinical trials are driven by research protocols; ambulatory care data collected during the course of a clinical trial may, therefore, be suitable for medical effectiveness studies. Clinical data bases contain observational data collected as a routine part of patient care; patients are not randomized and intervention is not prescribed (Kunitz, Gross, and Heyman, 1981). However, several of the existing clinical data bases are the products of observational studies that have utilized systematic data collection procedures, and they have been used to support a wide variety of research endeavors. Examples include the Duke Cardiovascular Diseases Data Bases and the ARAMIS (Arthritis, Rheumatism, and Aging Medical Information System) data bases. These clinical data bases have been used for epidemiological studies, such as the assessment of patient risk and postmarketing surveillance to evaluate adverse effects when a drug is used in general practice. For example, the ARAMIS data base was used to study the effects of azathioprine in patients with rheumatoid arthritis (Tierney and McDonald, 1991). In this application, instead of relying on the physician to report adverse effects from the use of this new drug, patients given early prescriptions of the drug noted in the data base were surveyed to get a more complete picture of the responses (Moses, 1991).

Practice data bases are another form of clinical data base and are distinguished from observational data bases. The practice data base contains data collected as a part of routine care but not necessarily according to a common data collection protocol. These data bases reflect variations in physician practice, resource consumption, quality assurance, and the effects of cost reduction on quality of care. In a study at the San Francisco Veterans Administration Hospital, the practice data base was a better predictor of hospital costs than were the diagnosis-related groups (DRGs) (Tierney and McDonald, 1991). Practice data bases have been used in physician decisionmaking and in collaborative clinical research. In the latter, they have served as a pool of subjects for clinical research protocols.

Advocates of using clinical trial data (Byar, 1991) find a number of problems with observational and practice data bases that, in their opinion, compromise their utility. Although it is true that observational data bases are compiled by health care institutions, contain timely data generated during the normal course of care, and pool data from a variety of institutional sources such as the laboratory, pharmacy, and medical record, they lack the randomization and treatment intervention necessary for determining treatment efficacy. They are, however, useful for medical effectiveness research.

Three major issues need to be addressed in the use of practice data bases: data issues, patient issues, and bias.

Data Issues

In general, practice data bases were not developed for the research purposes for which they are used. Research questions are not generally formulated prior to data collection, and therefore data may not be available to answer these questions (Pryor and Lee, 1991). Data are recorded only when patients contact a particular aspect of the health care system. Therefore, data may be missing

because (1) providers are outside of that particular part of the system, (2) the patient chooses not to visit a health care facility, or (3) eligibility criteria have changed, and the patient can no longer receive health care there. It is therefore not possible to judge if the patient is not visiting that particular health care provider, is being treated elsewhere, or is not being treated at all. In addition, patients who are less ill may visit the health care facility or provider less often, and thus, data may be more representative of sicker patients. Patients and therapies are not randomly assigned, and the resulting bias can seriously affect the quality of the data (Tierney and McDonald, 1991).

The contents of the data sets from different sites may vary considerably. Consistent definition of variables and quality control are minimum requirements for aggregating data (Muhlbaier and Pryor, 1989). The lack of consistency requires that attention be given to quantifying and controlling for differences in the data. It is likely that the schedule for data collection will also vary across sites, and thus, interpretation of the effect of interval differences in data collection must be assessed.

Decisions as to the comparable value of multiple measures of the same parameter must be made, and a plan to operationalize that choice must be implemented carefully (Tierney and McDonald, 1991). In addition, a decision as to the level at which measures are aggregated is important (McDonald and Hui, 1991).

Missing data present a particular problem in the use of observational data bases. Missing data may reflect data not collected, data lost or garbled at entry or transmission, or data that are not applicable for a variety of reasons (McDonald and Hui, 1991). The mechanism for selection of missing data is generally not known, and bias can be introduced into the study.

Patients' Issues

Historically, practice data bases have contained fewer patient.data than have claims data bases, and they have been limited to the individual facility housing the system. Larger data bases, like claims data bases, are more sensitive to low frequency medical conditions, but practice data bases are more likely to identify clinical changes in patients. Most practice data bases, especially research-focused ones, are located in academic medical centers and contain information on patients who are not representative of the general population; that is, they are more likely to have a lower socioeconomic status. Providers are more likely to be residents and their teachers, making them unrepresentative of most practicing physicians. However, these limitations of practice data bases will be addressed when collaboration between academia and general practice occurs with more regularity, and individual data bases are linked to provide a much larger sample (Tierney and McDonald, 1991).

Bias

Selection of patients by providers for diagnostic procedures and treatments introduces bias into the natural history of disease and treatment (Tierney and McDonald, 1991). Obviously, physicians will choose only patients for whom they think a treatment will be beneficial (McDonald and Hui, 1991). This is one of the shortcomings of observational studies (Byar, 1991). Models can be derived to control for this bias and negate the deficiency in observational studies.

Although RCTs decrease the treatment bias by using random allocation of patients, bias may exist in RCTs as well as in observational studies. Participation in an RCT is based on well-defined eligibility criteria that define a uniform population for study. This may limit the generalizability of the results of the study. In the Coronary Artery Surgery Study (CASS) (Kronmal, Davis, Fisher, and others, 1978), patients who were entered into the RCT were compared with those who met the eligibility criteria but were not randomized. Researchers found that randomized patients differed from randomizable patients in prognostic factors, especially in severity of cardiovascular disease and symptoms.

Until recently, randomization was done in an unblocked fashion which often produced subsets that were not balanced in all strata. Nonsignificant imbalances in powerful prognostic factors can lead to bias. Now that randomization is performed in blocks within the identified subsets, the introduction of bias in this manner is less likely to occur.

If subgrouping of patients in an RCT is performed after randomization has taken place, results may be misinterpreted. This is especially true when overall group differences are not significant, or only marginally significant, and the subsets are small.

A more technical cause of bias lies in the use of nonlinear statistical models in RCTs. These models may yield an estimate of treatment effect when important covariates are accidentally omitted (because they are not identified) from statistical analyses. In addition, failure to recognize if there is a treatment by covariate interaction in both linear and nonlinear models may yield bias (Hlatky, Lee, Harrell, and others, 1984).

Addressing Problems with Practice Data Bases

A number of methodological issues relate to the use of automated data bases in ambulatory care effectiveness studies. Research using data bases would be enhanced if methods for acquiring better data were designed. Prospectively collected data, with clear definition and detailed specifications, and a protocol for their collection would be valuable. Careful choice of collaborators and sites and a plan to control or allow for interfering variables would improve data quality (Moses, 1991). This description conforms, in many ways, with that of a clinical trial. In the observational data base, however, all the patients' data would be included, and no attempt to select patients or randomize them to treatments would occur.

Time, as a formal dimension, is an important aspect of longitudinal, observational data bases in which time series analysis across many patients is necessary. Analyses of trends over time for mortality, morbidity, disability, expenditures for health care, and variations over geographic areas have been carried out. Krakauer and Bailey (1991) have performed univariate time to event (treatment, hospitalization, readmission, death) on Health Care Financing Administration files (Medicare and Medicaid) to monitor trends over time and assess interventions.

A complete uniform data set permits the most credible and productive analysis, and therefore, attempts to deal with missing data are of particular importance. As described earlier, a prospective study with standardized definitions would assist in the collection of a complete set of data. In some cases, prospective data collection was undertaken to augment data from a practice data base to deal with missing data; however, this is an expensive and not always practical approach. In other cases, objective data are substituted for subjective data. For example, a chest x-ray can reflect a diagnosis of congestive heart failure even when the diagnosis is missing from the medical record. A study assessing the quality of data excerpted from medical records found that subjective, ambiguous, or incomplete data were subject to the most errors in excerpting and coding, resulting in a great deal of missing or unusable data (Horowitz and Yu, 1984).

Missing data have sometimes been addressed by supplementing the practice data base with data from a claims and/or national data base. This link to a large data base allows for inference of missing data. It does, however, assume that definitions across data bases are standardized. The Agency for Health Care Policy and Research and the American Society for Testing and Materials, a national consensus standards organization, are attempting to develop a standard structure and format for transmitting clinical data (McDonald and Hui, 1991). In some studies, variables and/or patients with missing data have been eliminated from the study. However, this may introduce bias or compromise the power of analysis and therefore is not an approach of choice (Pryor and Lee, 1991).

In many studies, missing data are addressed by imputing a value from the respondent's mean or from a predicted value. Safran (1991) suggested that multiple imputation for nonresponses is a more reliable method for dealing with missing data. In this way, missing values can be replaced by two or more plausible values. The values can represent uncertainty about which values to impute, assuming the reasons for nonresponse are known.

To enhance the predictive method, assess the quality of the prediction, and design a validation strategy, it may be necessary to employ innovative methods of analysis. Given the different types of data available (for example, binary, ordinal, continuous), it is possible to use such methods as subgrouping or stratification, regression modeling strategies to adjust for large numbers of variables, Bayesian approaches, pattern recognition, and dynamic approaches.

Innovative methods for improving predictive methods include: employing less restrictive methods regarding the distribution of dependent and independent variables and their relationship to each other, using superior information for dependent and independent variables, adjusting for differences between groups, using dynamic approaches such as repeated measures and time covariates, using more

clinically interpretable data, and predicting the likely yield of tests before they are ordered. In addition, innovations within methods are suggested to verify the model assumptions about the distribution of variables involved or the nature of the relationship between predictor variables and outcome variables (Pryor and Lee, 1991).

A method is needed to assess and compare the quality of predictors. For this, it is necessary to compare precision or repeatability, including the confidence limits of a prediction, the reliability (that is, how close a prediction is to the actual value for a patient), and discrimination (that is, the ability to separate patients with or without a specific outcome).

Validation strategies should address the generalizability of a prediction. Internal methods of generalization provide for use of the model on the same population for whom it was developed to validate the model. With this method, applicability of findings to new patients cannot be described. External methods of validation apply the model to new and different populations to evaluate its performance (Pryor and Lee, 1991).

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6. Selected Automated Ambulatory Medical Records Systems

This chapter describes selected automated ambulatory medical records systems (AAMRSs) and related systems that have potential to support medical effectiveness research in ambulatory settings. The descriptions focus on the system of records or the computer and manual processes that surround automated recordkeeping including inputs, outputs, and processes.

Included in the descriptions are the following systems: ARAMIS, ATHOS, BICS, BIHS, CIS, COSTAR, DIOGENE, HCHP/AMRS, HELP, MARS, PIMS/PIPS, RMRS, RPMS, STOR, THERESA, TMR, and VIPOR.

Descriptions are based on a literature review, as well as information from the system "owners" and not on an indepth study of the documentation of each system. As indicated in the text of each description, most of these systems have not been applied to medical effectiveness studies, perhaps because this is an emerging field. The systems, however, do contain clinical data, documenting the clinical course of a patient, and could be useful for medical effectiveness studies. The utility of these systems will generally be enhanced if medical records systems "owners" and clinicians agree to administer outcomes questionnaires to their patients.

System: ARAMIS

Arthritis, Rheumatism, and Aging Medical Information System
Stanford University Medical Center, Palo Alto, CA
Primary Contact: J. Fries, M.D.

This system was developed to support clinical research in chronic diseases and is a prototype of a national chronic disease data bank. ARAMIS contains longitudinal, observational data for rheumatic disease obtained from multiple, collaborating, university-based and private medical clinic settings collected with the Time-Oriented Record (TOR). It provides a uniform data base of rheumatic diseases. Data reflect stratifying, intervention, and outcome measures. The system has a descriptive vocabulary and data dictionary with a series of associated glossaries and administrative manuals documenting ascertainment and scoring rules for all data elements within the data base. As of 1991, ARAMIS contained 17 data banks from the United States and Canada. Within the system, data are shared on over 25,000 patients.

Characteristics. The system was developed from 1970 to 1975. Currently, the data banks reside in Medlog, a commercial product developed by Information Analysis Corporation from the original data base management system TOD (Time-Oriented Database). Medlog, written in C, supports both direct and remote data entry, editing, retrieval, statistical analysis, and graphics.

Data include laboratory and therapeutic information as well as other quantitative data and qualitative clinical observations. Medical histories are self-administered by patients and are reviewed by physicians. In addition, a Health Assessment Questionnaire (HAQ) is used on a regular basis to collect information on disability, discomfort, iatrogenic conditions, economic impact, and mortality. Data are entered from TORs, used by clinicians in each of the clinical entities, or ported from computer-based medical records systems.

Retrieval is accomplished through a transposed file using time-oriented subsetting and analytic techniques. Data may be ported to the standard statistical packages SAS, BMPD, or SPSS or may be analyzed directly via a series of built-in interactive statistical programs within Medlog.

Comments. Although ARAMIS is limited to arthritis and rheumatology, the system contains data from multiple ambulatory care settings and provides a model for a chronic disease ambulatory care and research data base. Studies conducted on clinical research have produced over 477 publications. Although ARAMIS is not an automated medical records system, since it was not developed to support care, therapeutic effects have been studied and the data contain many of the same features as those collected through AAMRSs.

System: ATHOS

AIDS Time-Oriented Health Outcome Study
Stanford University Medical Center
Palo Alto, CA
Primary Contact: J. Fries, M.D.

This system was developed under a grant from the Agency for Health Care Policy and Research (AHCPR) to support clinical research and health services research in acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infection and is a prototype of a national long-term AIDS data bank. It contains longitudinal, observational data for HIV and resulting disorders obtained from multiple collaborating private practice and university-based clinics. Data are collected via TORs or from electronic medical records systems (MAC-based Therapy Management System [TMS] or DOS-based QD Patient Management System). Data reflect stratifying, intervention, and outcome measures in AIDS. It has a descriptive vocabulary and data dictionary with a series of associated glossaries and administrative manuals documenting ascertainment and scoring rules for all data elements within the data base. As of 1991, ATHOS contained five data banks from San Francisco, Los Angeles, and San Diego. Within the system, data are shared on over 1,500 patients.

Characteristics. The system was developed in 1989. Currently, the data banks reside in Medlog, a commercial product developed by Information Analysis Corporation from the original data base management system. Medlog, written in C, supports both direct and remote data entry, editing, retrieval, statistical analysis, and graphics.

Data include laboratory and therapeutic information, as well as other quantitative data and qualitative clinical observations. Medical histories and physical findings are obtained by physicians in the clinical care setting using paper forms or direct input into the computerized patient management system. In addition, a baseline health history and self-administered, quarterly health assessment questionnaires (HAQs) are obtained from patients to collect information on disability, pain, quality of life, side effects, economic impact, health care utilization, and mortality. Data are entered from the questionnaires by clinic-based outcome assessors or directly by physicians into the patient management system with subsequent porting to the Medlog data banks.

Retrieval is accomplished through a transposed file using time-oriented subsetting and analytic techniques. Data may be ported to the standard statistical packages SAS or BMDP or analyzed directly via a series of built-in interactive statistical programs within Medlog.

Comments. Although ATHOS is limited to AIDS- and HIV-related disorders, the system contains data from multiple outpatient, inpatient, and ambulatory care settings and provides a model for observational data bases in AIDS. Studies are ongoing and include 10 publications and conference presentations to date. Use of the TMS and QD systems as part of this project provides prototypes for automated electronic medical records systems used to support patient care. The overall approach to health services research follows that of ARAMIS in terms of viewing long-term outcomes.

System: BICS

Brigham and Women's Hospital
Integrated Computing System
Boston, MA
Primary Contact: J. Teich, M.D.

The Brigham and Women's Hospital Integrated Computing System (BICS) contains broad clinical and administrative data bases which are used by nearly all departments in the hospital. The current version of BICS stems from the Beth Israel Hospital system, which was installed at Brigham and Women's Hospital (BWH) in 1985; BICS has been developed independently at BWH since 1988. The ambulatory record was developed in 1989 and now serves many of the hospital's practices with stations in every examination room. A new satellite ambulatory center, located a few miles from the hospital, is also served by the computerized record system through fiberoptic links. Specific ambulatory record information is currently available on 22,000 patients; other clinical information, organized and presented for ambulatory use, is available on any hospital patient.

Characteristics. BICS runs on a network of Data General Eclipse Computers, programmed in the MIIS dialect of MUMPS. Conversion of the entire system to a network of microcomputers, running standard MUMPS, is underway and will continue in 1993.

Data content includes condition, complications, medications, notes, allergies, health-maintenance

information, vital signs, and visit summaries. The visit summaries organize all available clinical data in a visit-by-visit fashion for review. Information can also be reviewed by problem and by data type. A provider's to-do list is also available for each patient. Specific flowsheets can be constructed for use in a given practice to handle specific data elements and viewpoints needed by that particular practice.

Data are entered by (1) direct typing by providers, (2) dictation—transcriptions are provided on disk and are uploaded for approval and display, and (3) data capture from other clinical areas (for example, laboratory, electrocardiogram [EKG], discharge abstracts). Security is through a password mechanism; providers who serve in the outpatient area are given security privileges to enter and edit data.

Comments. The system's data base architecture supports research use. There have not yet been studies which specifically use the ambulatory record information for outcomes evaluation, although there is outcomes research using other areas of the BICS data base. A system of health-maintenance standards and reminders, using the computer's health-maintenance data, is being developed.

System: BIHS

Beth Israel Hospital System
Boston, MA
Primary Contact: C. Safran, M.D.

Since 1976, the Beth Israel Hospital System has utilized a hospital-wide clinical computing system that supports inpatient and outpatient services. It is an integral part of patient care in the hospital and was designed with the primary goal of helping the clinician care for patients. This system for clinical computing is one of the most heavily used in the country. Clinicians use the computer to display test results over 40,000 times per week, send over 13,000 pieces of electronic mail, and perform over 1,000 literature searches. In 1989, the Outpatient Medical Record (OMR) system was added to the system, and it was specifically designed to encourage physicians to enter data directly into the computer.

Characteristics. The hospital system runs on a network of Data General Eclipse Computers that are interconnected and is programmed in the MIIS dialect of MUMPS. Terminals interface with the computer and are located in every physician office and examination room. This system was designed to permit the acquisition of information at the point of transaction. The data are then immediately available to the user who needs these data, be it the physician in an ambulatory office, the nurses at a nursing station, or a technician in the laboratory. The outpatient system supports appointments, vaccine eligibility reminders, flowsheets, progress notes (indexed to problems on problem list), and retrieval. Programs allow clinicians to enter and edit data and display problem lists, medications lists, and health promotion and disease prevention screening flowsheets. A confidentiality module restricts access to the system.

A key design feature of the Beth Israel Hospital's clinical computing system is that there is a common registry of patients; the system is truly integrated. The ambulatory data base can be shared with other systems throughout the hospital and vice versa. In practical terms, the results of the PAP smear from the cytology system, or the results of the mammogram from the radiology system, are available to the primary care screening programs; physicians do not have to reenter these data. In a similar fashion, physicians in the emergency room can immediately view a patient's problems and current medications.

The OMR system currently has problem files and medication files on more than 7,000 patients. Almost 90 percent of the faculty (15/17) and over 70 percent of the medical residents (35/48) routinely enter problem lists and medication lists for the patients they see. Less than 40 percent of the interns (9/24) routinely chart problems and medications on the computer.

Notes and letters that are dictated by faculty physicians are now transcribed onto the system. Additionally, clinicians type over 700 progress notes each month directly into the computer.

Comments. Studies show that physicians type twice as much on the computer-based problem lists than they wrote in the paper counterpart. These studies do not have any data to suggest why a minority of clinicians still do not elect to use the computer system.

Both process and outcome variables for all patients are routinely recorded. Ambulatory services and charges the patients incur (for example, emergency room visits, number of tests, medication dispensed) are recorded as well as hospitalizations, discharge diagnoses, procedures, charges, and discharge destination. The ambulatory practice at the

BIH is committed to a complete transition to a paperless record, and the above data suggest this process is well underway.

System: CIS

Clinical Information System
Columbia-Presbyterian Medical Center (CPMC)
New York, NY
Primary Contact: P. Clayton, Ph.D.

CPMC is developing a clinical information system (CIS) with decision support applications that continuously monitor patient data as they are added to a patient-oriented clinical data base. In addition to a longitudinal patient data base, the system also contains a medical entities dictionary, a collection of Medical Logic Modules (MLMs), and a common results review function.

Because CIS is part of an Integrated Academic Information Management System (IAIMS) being developed at CPMC, the user can also access university and hospital administrative functions, basic research applications, and library services from the same workstation which is used to access clinical data. There are over 50 hosts or servers and 1,000 workstations on the CPMC/IAIMS network. The system is heavily used for patient care; on a daily basis, there are over 7,000 inquiries by over 1,000 individuals.

Characteristics. CIS keeps all data for patients available online indefinitely regardless of whether the patient is seen in the hospital, emergency room, or outpatient clinic. Data are acquired from other clinical systems (clinical laboratory, radiology, pharmacy, and so on) via Health Level Seven communications. Most of the current results are narrative rather than coded, but the new applications that are being developed and added use increasing amounts of coded data. There is a minor amount of physician data entry. The central patient data base has a small number of tables, each with a small number of general purpose columns. A controlled vocabulary of "codes" and values are stored in the general purpose columns to represent various clinical data items such as diagnostic findings, vital signs, and medications. This philosophy was adopted to permit online decisionmaking and to accommodate the growth expected as more of the patient record becomes computer-based. One of the defining characteristics of the system is a Medical Entities dictionary which is based on extensions of the National Library of Medicine UMLS. The definition of vocabulary terms supports multiple parents for an entity, codes for an entity that may have many synonyms, and inheritance of properties.

The clinical data base (which started on a hierarchic proprietary PCS-ADS platform) is now built on a relational platform with an extra level of indirection to optimize clustering of data by patient and to allow new entities to be stored in the data base without modifying tables. The calls to this data base are based on structured query language (SQL).

Interpatient queries (population analyses) are accomplished by periodically downloading extracts from the patient-oriented data base into relational data bases with more traditional design.

Data are gathered from multiple ancillary systems but are stored in a central data base which supports a common results review program. In the instance of failure of one of the data base hosts, an automatic, redundant network path to the primary source assures that the data are always available. The decisionmaking system and data base reside on IBM mainframes but have been designed to be portable.

Comments. CIS can be used for online decisionmaking and has a growing capacity for medical records and interpatient queries. This system demonstrates a potential for medical effectiveness research.

System: COSTAR

Computer-Stored Ambulatory Record
Laboratory of Computer Science
Massachusetts General Hospital
Boston, MA
Primary Contact: J. Campbell

COSTAR was developed by the Laboratory of Computer Science at Massachusetts General Hospital and was implemented in 1968 at the Harvard Community Health Plan (HCHP). It was one of the earliest systems capable of producing an automated computer-based patient record designed to replace the paper medical record. This modular medical information and record system is available commercially and is in the public domain. It is one of the most widely used automated ambulatory medical records systems.

The system is distributed and enhanced by the COSTAR Users Group which has a mailing list of 750 and a current membership of more than 100

individuals and organizations. The country of Malta has implemented COSTAR as the national public health record, and a network of welfare offices in southern California uses COSTAR as the sole record resource. There are between 200 and 500 sites in the United States, Canada, Europe, and Australia. An exact tally of sites is impossible because of the public domain distribution policy.

Characteristics. The system, developed between 1968 and 1978, uses MUMPS on both VAXs and personal computers (PCs). It is modular in design, permitting system tailoring and phased implementation. The six modules include: (1) security and integrity, (2) registration, (3) scheduling, (4) medical record, (5) billing and accounts receivable, and (6) Medical Query Language (MQL). MQL is a useful resource for COSTAR but is not part of the public domain package and requires a site license to install. Individual sites can select the portions of the system they wish to install. Current release 5.9 has undergone periodic revisions since the first public domain copy in the 1970s and now includes an automated reminder system. The system supports codified clinical information in seven major divisions: physical findings, diagnoses, laboratory tests, medications, nonmedical therapies, procedures, and personal history. COSTAR has a dictionary of medical terms that each user group may define for its own needs. Each element in the dictionary corresponds to a unique COSTAR code.

Computer-printed encounter forms are used by clinicians for data capture. Administrative and medical data are included on the self-encoded forms. Office visits, telephone calls, home visits, and hospital stays are entered into the system either through the encounter form or from narrative dictation. The narratives and/or encounter forms are entered by medical records department clinical personnel. MQL supports complex searches of the data base and retrieval.

Comments. There are some concerns about the cost of COSTAR in private practice and small clinic settings (Dambro, Weiss, McClure, and Vuturo, 1988), although it has been argued that not all benefits were factored into the cost estimate (Tierney and McDonald, 1991). COSTAR has served as a base for many medical records developments including public and occupational health systems, veterinary practice systems, and problem-oriented records systems. Research groups have developed within the COSTAR community. The largest effort dedicated to medical research interests is a collaboration of 30 sites in the United States and Canada conducting research on multiple sclerosis. This collaborative effort has resulted in a data-sharing agreement, pooled research projects, and pending publications. The system has been used for clinical studies (Payne, Goroll, Morgan, and Barnett, 1990) and can support medical effectiveness research.

System: DIOGENE

Division Informatique Hôpital Genève
University Hospital of Geneva
Geneva, Switzerland
Primary Contact: J. Scherrer, M.D.

DIOGENE is a government-sponsored hospital information system with goals to reduce average length of stay and improve operations. It was introduced in 1974 with applications added through 1988. It is a comprehensive hospital information system of automated medical records. DIOGENE supports inpatient and outpatient services and utilizes a fully integrated data base.

Characteristics. DIGENE is housed in 2 CYBER 180/845s, 9 satellite computers operating under UNIX, 113 ward unit stations, and 454 connected personal computers and terminals. It is written in BABEL, a locally developed language, and is supported by an Intersat Network that links all computers in the system. The system supports all hospital data functions. Security procedures involve a strict protocol for access to data.

The system interface is an operator pool that enters data or processes requests for information. Nurses and other clinicians call the operator from the ward or clinic via a telestation and update all information. The operator enters the data directly, and the entered information is displayed on the terminal. At the completion of the dictation, the clinician suggests any changes and then approves the text which becomes a permanent part of the computer-based patient record. Information is retrieved in a similar fashion and displayed on the terminal. Recently, in a pilot study, physicians entered diagnoses and procedures directly into the system.

Comments. Since this system contains an automated medical record, it would seem most useful for clinical and medical effectiveness studies. Documentation reviewed thus far, however, does not address research uses of the system.

System: HCHP/AMRS

Harvard Community Health Plan Ambulatory Medical Record System, Brookline, MA
Primary Contact: K. Coltin

AMRS was adapted from the Computer-Stored Ambulatory Record (COSTAR) system developed by the Laboratory of Computer Science at Massachusetts General Hospital. After COSTAR was used for 10 years, a major change in the technology of the HCHP system was implemented in 1978; however, the functionality of the COSTAR system (Version IV) was essentially replicated in the new AMRS system.

AMRS currently functions as the ambulatory medical record for patient care encounters occurring in 11 health centers serving approximately 250,000 active members and providing approximately 1.5 million office visits per year. Historical medical information is available for over 800,000 patients for varying time intervals over 20 years. Hospitalization data are not captured in AMRS on a regular basis and are routinely available only from a separate automated claims system.

Characteristics. The AMRS system was housed on 12 DEC PDP 11/84s networked through Ethernet to each other and to a VAX server. The AMRS system was to be connected to VAX hardware in the spring of 1992. The operating system on the PDPs was ISM M/11+ (Version 3.4), and the language was Standard MUMPS.

Through the VAX server, the AMRS network is also networked to separate enrollment/billing, laboratory information, and referral/authorization systems. All of these systems feed data electronically into the AMRS patient record.

Data on diagnoses/problems, therapies, and procedures occurring at health center encounters are recorded by the clinician on paper encounter forms, which are encoded and input by medical records personnel. In addition to the coded problems, therapies, and procedures, both free text comments (up to 180 characters) and longer, dictated notes are code-linked and input to AMRS.

Medications prescribed at health center visits or by telephone are recorded by the clinician in the therapies section of the encounter form and input by medical records personnel to AMRS, and prescriptions filled at HCHP pharmacies are input by pharmacists to a separate automated pharmacy system.

Laboratory and x-ray orders are recorded by clinicians on a laboratory or radiology request form. Radiology results are input directly to AMRS, and laboratory requests and results are input to a laboratory information system and fed electronically into AMRS. Results for outpatient tests performed outside the health center are sent to both the ordering clinician and the medical records department, where they are entered into AMRS.

Query and data retrieval functions on AMRS are supported by the Clinical Analysis Support System (CLASS) which has been developed and enhanced by HCHP over the past 12 years. The CLASS query software permits the identification of an enrollee/patient population on the basis of defined demographic, enrollment, utilization, and/or clinical code characteristics. Various data output options (for example, lists, labels, full medical records or selected excerpts, reports, files) may then be produced for the defined population. CLASS includes a file extract utility which produces predefined, fixed format text files. Either ASCII text files for downloading to a PC or ASCII or EBCDIC text files written to magnetic tape may be produced. Several different file extracts are available (for example, medical encounter data, prenatal data, membership/demographic data, laboratory test result data). These files can be read by almost any PC or mainframe software package.

Similar query and file extract utilities have been developed on the automated claims system for downloading hospital and outside outpatient claims data to PCs.

Routine file extracts from the HCHP automated pharmacy system are written to magnetic tape for analysis on a mainframe system at Brigham and Women's Hospital, as part of a Joint Pharmacoepidemiology Research Program.

Comments. Numerous research and management studies have been conducted utilizing HCHP data files which were extracted from these diverse and technically incompatible clinical information systems and subsequently linked and merged for analysis in either a PC or mainframe environment. DBase IV and PC-SAS have been used extensively with these files on PCs, and SAS and SPSS have been used on mainframes.

System: HELP

Health Evaluation Through Logical Processing
University of Utah and Intermountain
Health Care Corporations
LDS Hospital
Salt Lake City, UT
Primary Contact: T.A. Pryor, M.D.

HELP, an integrated hospital information system, designed to serve both the clinical and administrative needs of the hospital, has been in development and use since the late 1950s and early 1960s. The primary objective of HELP is to provide medical decision support. It has a flexible medical dictionary and decision support imbedded in the system.

Characteristics. The system is a common integrated data base system with terminals in every nursing division. In 1981, it was converted to Tandem computers. The data base is hierarchical in structure. There are plans to move toward distributed processing and a micro-based HELP system in physicians' offices for followup. The system contains more than 100,000 rules and processes pertaining to a broad spectrum of health care to assist in decisionmaking. The system contains a language for processing and assisting with medical decisions. It supports admissions, discharges, transfer, order entry, medical records, and clinical data.

Professionals, primarily nurses, enter quantitative and procedural data directly into the system using terminals. In addition, HELP interfaces with financial, laboratory, and intensive care unit monitoring systems. Only minimal history and physical examinations are contained in the HELP record. Outpatient data are captured, although these data may be limited reflecting the limited outpatient settings of the hospital. Retrieval is supported through a query system called STRATO.

Comments. HELP, although primarily a hospital information system, can support medical effectiveness research, since the hospital's outpatient clinics are included in the system. As care evolves to an outpatient setting, physician-office interfaces are planned for the system. The system's emphasis on decisionmaking support should be of interest to medical effectiveness researchers.

System: MARS

Medical Archival System
University of Pittsburgh
Pittsburgh, PA
Primary Contact: J.K. Vries, M.D.

MARS is a large-scale medical data archiving system that integrates patient data from central transcription, laboratories, pharmacy, radiology, and other departmental systems. It was implemented in 1989 in both inpatient and outpatient environments, and its development continues.

Characteristics. MARS is a distributed, parallel processing data archival and retrieval system. It has a fiberoptic data communications network running on a heterogeneous network of 45 computers serving over 800 terminals (2 DEC System 3100 and 4 micro VAX II computers) and 32 Unix workstations.

Data are entered from transcription and dictated report files, as well as departmental systems. Plans are to enter nursing protocols also.

Medical records are online. Data base users enter searches or other commands at user interface workstations and computers that execute the MARS client interface processes which in turn search the data base and provide the outputs (client-server model). Although a full range of retrieval options is not yet available, data can be extracted for links to statistical packages and research.

Comments. This system is still under development using state-of-the-art technology. Plans are to continue development of programs for automated medical records coding and for generating International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes or QMR (Quick Medical Reference) diagnoses, and procedures coding. Theoretically, this system can support medical effectiveness research.

System: PIMS/PIPS

Patient Information Management System/
Patient Information Protocol System
Loyola University Medical Center
Maywood, IL
Primary Contact: A. Chandrasekhar, M.D.

Development of the Patient Information Management System (PIMS) and Patient Information Protocol System (PIPS) started in 1989 within the Department of Medicine at Loyola University's Stritch School of Medicine. The system's design

goals were to integrate departmental and host-based patient data into an electronic medical record for outpatient care and longitudinal clinical research purposes. As of 1991, the system contained information on a patient population of approximately 80,000 and had 67 defined disease or research protocols.

Characteristics. The system is based on Revelation Technologies' data base management system—Advanced Revelation (AREV). The system operates within a medical center-wide local area network (LAN) environment with approximately three gigabytes of data distributed among four Intel 386/486 file servers. The entire LAN operates under Novell Netware 2.15c and 3.11. The network supports approximately 250 workstations with 70 simultaneous data base users. Specific interfaces for PIMS/PIPS have been developed to support the electronic capture of clinical laboratory and admission/discharge information. The LAN environment and data base management system provide multiple layers of security and audit logging. Users can be restricted to specific accounts, physical workstations, and time periods. The system supports online data collection and codification through a wide range of user-defined tables (for example, Current Procedural Terminology [CPT] and ICD–9). The system also supports ad hoc queries and reports through AREV's English-like command language and SQL.

Physicians and support staff enter data directly into the system using predefined menus and collection windows. Integrated modules include demographics, current medications, problem list, prior events, clinical laboratory data, reminders, and online procedures. Prior events and problem lists can be captured automatically through interfaces with admissions, procedure, and charge capture systems. Users can initiate electronic capture of clinical laboratory data or may schedule automatic daily captures at predefined times. Patient data can be reported in a wide range of summary formats.

PIPS allows clinicians to define information protocols that address patient care practices or specific research projects. Protocols are a collection of data objects from user-defined categories (for example, physical findings, drugs or treatments, symptoms, toxicities, laboratory data, x-ray/scans, and lesions). Protocols allow for time-oriented collection and review of patient data and support data entry as individual values or full text progress notes. Protocol data summaries can be extracted for analysis using external statistical packages (for example, SAS).

Comments. Since one of the goals of this system is to support longitudinal studies, it would appear that it could be used for medical effectiveness research.

System: RMRS

Regenstrief Medical Records System
Indiana University Medical Center
Indianapolis, IN
Primary Contact: Clement McDonald, M.D.

This system began in 1972 with the goal of creating a "summary" computer-stored medical record. RMRS now contains records for all 420,000 registered patients of Wishard Memorial Hospital's outpatient clinics as well as patients of a neighboring Veterans Affairs hospital and Indiana University Hospital. The system processes laboratory tests, inpatient drug orders, outpatient prescriptions, and scheduling and contains the full coded diagnostic impression for most diagnostic studies. The full test is also available for some (for example, diagnostic radiology). Data are fully coded and defined in a data dictionary. Medical records are time-oriented. The system integrates problem lists, inpatient and outpatient records, charges, immunizations, and duration of visits.

Characteristics. The system is housed in cluster DEC VAXs to 8550 and 386 PC workstations, integrated through Ethernet. Languages include VAX BASIC and VAX Assembly Language. Microcomputers use Revelation R/Basic and Intel Assembly language. The medical records data base resides in Digital Equipment's Record Management System.

RMRS is part of a larger administrative support system that handles appointment scheduling and charge capture. Medical records, prescriptions, narratives, visits, laboratory records, and retrieval are supported through the system.

Nurse- and physician-collected data are captured on computer generated, time-oriented encounter forms and special multiple choice forms, and these data are entered by data entry specialists; however, physicians in the General Medicine Clinic and the inpatient internal medicine service enter orders directly through workstations. There are pharmacy and laboratory data and clinic computer subsystems within the RMRS. Tapes from the hospital case abstracting service also are entered in an automated manner. Radiologic procedures, EKGs, occult

blood, PPD (purified protein derivative) tests, spirometries, bone marrow diagnoses, cardiac echoes, vital signs, and weights are coded and entered manually by specially trained staff. The nature and location of a lesion are entered as well as trend data ("better" or "worse"), but not the details of the size and shape of each finding. Full texts of x-ray or surgical pathology reports and hospital admission histories and discharge summaries are also stored in the computer in a separate file.

Queries and data retrieval are handled in two ways: through a fast retrieval module within RMRS and through CARE, a medical query language. The fast retrieval module does not give an indication of time sequence and is, therefore, not appropriate for research. CARE serially searches the medical records and can be used for quality assurance as well as research. An extract utility interfaces with PC and mainframe SAS and BMDP.

Comments. This system was designed to automate the medical record and has become a hospital administrative and clinical information system.

Over 70 million observation records that detail clinical observations over time for more than 500,000 patients from 3 hospitals and a network of inner city clinics are stored. The data have been used to support research, and the system can be used to support studies of medical effectiveness. It is particularly noted for providing computer-generated reminders to physicians about clinical events that may require corrective action.

System: RPMS

Resource and Patient Management System
Indian Health Service (IHS)
Office of Health Program Research
and Development
ADP Systems Support Division
Tucson, AZ
Primary Contact: Bill Mason

An integrated group of automated data systems designed to operate on micro- and minicomputers located in any IHS or tribal health facility (that is, hospital or full-time clinic), the RPMS of the IHS will link health facilities to each other and to administrative units such as area offices. The main objective is to integrate patient care and cost data in a single automated data processing system that collects and stores a core set of health and management data which cuts across disciplines and facilities.

Characteristics. A typical RPMS configuration in a health facility might include the following systems: patient registration, pharmacy, dental, maternal and child health, contract health services, laboratory, and the patient care component (PCC). The PCC provides for the collection and storage, on local RPMS computers, of a broad range of health data resulting from inpatient, outpatient, and field visits at IHS, tribal, contract, and community sites. It is designed to support health care delivery, planning, management, and research. For health professionals, the PCC is a tool that assists in providing the type of care that addresses all of a patient's known health problems and preventive health needs. Planners use information such as the numbers of and reasons for various types of visits. Managers use aggregate information such as numbers of patients who have insurance and the types of insurance. Researchers use the information for a variety of locally designed projects. PCC data types include: date, type and location of visit, providers of service, measurements, diagnoses and procedures, health problems and treatment plans, personal and family history, reproductive factors, laboratory test results, and a variety of other health-related information. As with other RPMS components, the PCC utilizes the File Manager data base management system for data storage.

Key features of the PCC include: integrated data files, encounter forms, data entry module, a comprehensive health summary, patient registers, report generation, data transmission to the IHS data center, online help screens, and a diagnosis-related grouper program.

Comments. Although RPMS is one of the few automated ambulatory medical record systems available, it is not well known because support for the system has been insufficient to allow widespread dissemination of information about RPMS.

System: STOR

Summary Time-Oriented Record
University of California at San Francisco
San Francisco, CA
Primary Contact: Q.E. Whiting-O'Keefe, M.D.

STOR is a clinical information system that has operated in an inpatient and outpatient environment at UCSF since 1978. In 1985, it was approved for clinic-wide implementation in the university's ambulatory care clinics. In 1988, STOR contained

60,000 outpatient medical records and supported 22 clinic locations with 200,000 visits per year.

Characteristics. The system has been translated from MIIS into the MUMPS language (1989) and is housed in a Data General MV 40000. It uses LAN technology and a hierarchical record structure. It supports online real-time display for accessing clinical information. STOR gathers its data from eight existing ancillary computer systems.

STOR is a patient care-oriented system that replaces the paper ambulatory medical record in 85 percent of the patient visits and augments it the rest of the time. A master problem and therapy list was added in 1990. It supports a generalized problem and manifestation list, the elements of which are related in a hierarchical structure.

STOR contains a centralized summary data base of clinical information gathered from ancillary or departmental computer systems. Patient data are collected by providers using one of several computer-generated data display and capture encounter instruments that specialize according to clinical view, diagnosis, and clinician. These data are transcribed and entered manually into the system.

STOR's interpatient retrieval system, called SEARCH, has recently been upgraded to a complete query language.

Comments. This system has supported research and has been evaluated with positive results regarding accuracy of the medical record. It would appear that it can be used to support medical effectiveness research.

System: THERESA

Grady Memorial Hospital
Atlanta, GA
Primary Contact: D. Brizenbine

Development of THERESA was initiated in 1981 at the Emory University School of Medicine's primary clinical teaching facility. As of 1990, 18 million documents were online. It evolved from a decision-aiding system called Medical Aggregate-Record Inquiry (MARI). THERESA supports problem-oriented, task-oriented, event-oriented, and time-oriented views of the patient record along with English-like queries. It can describe usage patterns for each individual drug item and each category of drugs in the pharmacy. In addition, the system can track numbers of tests performed along with the reasons for analysis.

Characteristics. The system is based on a custom-made object-oriented data base management system that was designed to address problems associated with the paper patient record. It is housed in a distributed network of super minicomputers. It was developed by Medical Systems Development Corporation of Atlanta and is housed on four VAX 8550s and one VAX 8530 that support 1,000 terminals. Security is provided by allowing access to appropriate users at specific times and specific hospital locations. Further, the system checks the person who is accessing data and can shut off the computer for unauthorized access. The design of the system is based on a data dictionary of table-driven code systems that supports an array of file and data structures.

Physicians and other clinicians enter data directly into the system using "windowing" and mouse functions. Patient records include medical history, physical examination, diagnosis, radiology, pharmacy, orders, results, and progress. They also contain physician and nursing notes.

Comments. Although this system is not described in the literature with the same intensity as the other academic systems, it is a robust system and would appear to be capable of supporting medical effectiveness studies.

System: TMR

The Medical Record
Duke University Medical Center
Durham, NC
Primary Contacts: W.E. Hammond, M.D. and D. Pryor, M.D.

TMR is a comprehensive medical information system that supports patient care, administrative management, and clinical research. Its original design goal was to eliminate the paper medical record in an outpatient setting, and it has been developed in an evolutionary fashion over the past 21 years to support inpatient settings. It manages all aspects of the patient encounter including appointments/scheduling, diagnostic workup, and treatment in both the outpatient and inpatient environments. The Duke Cardiovascular Data Base, which has supported numerous clinical studies, was migrated to TMR in recent years. TMR is used at over 25 sites in the United States and Canada.

Characteristics. TMR operates on DEC's VAX under VMS and IBM PCs with DOS. It uses the GEMISCH data base management language and has a user-controlled data dictionary and text table. The system can store and retrieve any data contained in a traditional paper record with the exception of images such as x-rays. TMR can support a complete list of diagnoses and procedures, as well as subjective and physical findings, laboratory data, and therapeutic interventions.

Data can be entered interactively by secretaries, nurses, technicians, and physicians. Demographic data, research protocols, problems and diagnoses, subjective and physical findings, orders, therapies, encounter data, and accounting data are entered. Patient monitoring, laboratory, and other ancillary system data are entered directly.

The system's retrieval capabilities facilitate multiple views of the data from a problem, time, task, or encounter perspective. The system can generate discharge notes, referral letters, and other text reports and can initiate a protocol through decision rules. Queries are supported.

Comments. TMR is used to support research and can support medical effectiveness studies.

System: VIPOR

Vermont Integrated Problem-Oriented Record
University Health Center (UHC)
Burlington, VT
Primary Contact: T. Peterson, M.D.

VIPOR was originally implemented in 1986 at the UHC, the academic practice plan for the University of Vermont, to assist in the goals of patient care, education, and research. UHC was the first test site for IDX Corporation which developed the electronic medical record. The UHC Version, VIPOR, has allowed primary care groups distant from the central site to share a common patient data base and maintain access to laboratory and x-ray data electronically. It allows entry for both dictionary (coded) information and free text in a problem-oriented fashion facilitating both academic and patient care applications.

Eleven specialty groups use VIPOR, two for data entry and retrieval, the remainder for data retrieval. Currently, there are over 200,000 records in the VIPOR data base, and UHC has 383,000 annual ambulatory visits.

Characteristics. The system runs on a VAX 8550/VAX 6510 combination and is linked locally to six distant sites using an EtherNet arrangement; 440 ports are maintained for 1,200 users. VIPOR is written in MUMPS and can be queried using MQL. Data entry, retrieval, and report functions, as well a commercial drug interaction program, are supported by the system.

Data entry is allowed by user, tape, and transcription. Retrieval is at deskside and by designed reports. Sections include problems, notes, flow sheets, allergies, medications, immunizations, laboratories (by tape), radiology, and patient education. Demographic and financial information are shared with business software. Data may be displayed in secondary formats to aid interpretation.

Comments. The primary use of this data base thus far has been for clinical and educational purposes. It is intensively used as the primary medical record for the Department of Family Practice and is used by the same group to document educational experiences and to facilitate chart review and audit. Family Practice and Radiology have used VIPOR for quality assurance studies, but no cost effectiveness or outcome analyses have been performed. Nonetheless, the data base is considered to be a unique and largely untapped resource.

Solutions that will allow greater research effectiveness include expanded recovery systems for laboratory data and the use of more sophisticated data search capabilities such as SQL. A statistical system for online analyses or offline for downloaded files is not available at this time.

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